UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL 2804
	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' CONSOLIDATED MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT ON PROOF OF CAUSATION (DKTS. #S 1869, 1897, 1941)

July 31, 2019

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Statutes

Rules

Other Authorities

I. INTRODUCTION

The evidence set forth herein establishes, or at least creates a genuine dispute of material fact, that the conduct of Defendants collectively, and each Defendant separately, was a substantial contributing factor in causing the opioid epidemic and the harms directly suffered by Cuyahoga and Summit Counties. The Defendants, through a deceptive and illegal marketing campaign and failure to prevent diversion of their deadly drugs, created an excessive demand and supply of prescription opioids which led to dangerous and inappropriate licit and illicit use of prescription and non-prescription opioids. Plaintiffs were left to clean up the terrible consequences as best they could, suffering increased costs for police, criminal justice, addiction treatment, children and family services, first responders and many other harms.

Plaintiffs present several categories of proof, each separately sufficient to establish causation. Several prominent economists and public health experts use both aggregate and individual evidence to demonstrate the causal chain. Evidence from Defendants themselves establishes intentional and negligent conduct that would be expected to cause, and indeed did cause, and continues to cause, the Counties' injuries and the current public nuisance. In such circumstances, juries are responsible to decide causation, for that "is one of the things that juries do best." *Pacific Shores Properties, LLC v. City of Newport Beach*, 730 F.3d 1142, 1168 (9th Cir. 2013).

II. STATEMENT OF FACTS

A. THERE IS EXTENSIVE EVIDENCE THAT THE MANUFACTURERS COLLECTIVELY, AND EACH MANUFACTURER SEPARATELY, ENGAGED IN A FRAUDULENT MARKETING CAMPAIGN TO PERSUADE DOCTORS TO PRESCRIBE OPIOIDS.

Extensive evidence exists, and is set forth in great detail herein and in Plaintiffs' expert reports, that the Manufacturer Defendants engaged in a widespread promotion and marketing campaign that

trivialized the medical risks of addiction and exaggerated the benefits of long-term opioid use.[1] The goal of this campaign was to persuade doctors to expand their prescribing of opioids for all types of pain, at higher dose levels, and for longer periods of time. Defendants utilized a multi-prong approach to encourage liberal use. They engaged in direct-to-consumer marketing. They marketed directly to physicians through sales representative detailing. They directed, funded, and disseminated research, established pain-related medical societies and continuing medical education (CME) courses, and deployed "thought leaders" or "key opinion leaders" (KOLs), all to spread the misleading and ultimately tragedy-inducing message that the risk of addiction was rare, and that the benefits of long-term opioid use were scientifically supported.

1. The Manufacturer Defendants Engaged in a Misleading Marketing Campaign to Deceive Doctors and Patients about the Addictive Risks of Prescription Opioids.

For most of the 20th century, there was consensus that opioids should not be used for management of chronic pain because of the lack of scientific support regarding effectiveness and the well-established risk of addiction. *See* Report of Dr. Anna Lembke, Dkt. # 2000-10 at 9-10 (opioids "prescribed . . . sparingly" and "then only for short term use in cases of severe injury, surgery or at the very end of life"); Report of Dr. Mark A. Schumacher, Dkt. # 2000-24 at 14-16; See Report of Dr. David T. Courtwright, Dkt. #2000-3. To expand the market for opioids, Defendants recognized they needed to change the way doctors viewed and treated pain. Purdue's focus groups just prior to the release of OxyContin in 1995, found that "addictive potential" was the "biggest negative" to doctors prescribing OxyContin for non-cancer pain. *See* Agreed Statement of Facts, *United States v. Purdue Frederick Co.*, No. 1:07-cr-00029, Dkt. 5 (W.D. Va. May 10, 2007) ("Purdue Guilty Plea") at § 19. Thus, expanding the market for opioids meant convincing doctors that pain was undertreated and

[1] Plaintiffs do not purport to identify herein all the evidence on these points, but only enough evidence to establish a genuine dispute of material fact as to causation. Additional (but not all) evidence may be found in Plaintiffs' responses to the separate summary judgment motions filed by the individual Defendants. *See* (PSJ1-PSJ19).

that high potency opioids manufactured by Defendants could be used long-term, at high doses, with little risk of addiction.[2]

As Endo's marketing materials explained, sales of its long-lasting opioid medications would "depend directly on prescriber's comfort level with risk of abuse and diversion" and doctors would need to be convinced that "failure to manage chronic pain aggressively may result in ongoing pain, poor functionality, and patient desocialization." Ex. 1, ENDO-OPIOID_MDL-04095507 at 17; Ex. 2, KP360_OHIOMDL_000345871-6056 at 5989. Teva felt the same about how to expand its sale of generic opioids, developing a Discovery Channel documentary, "Pain Matters," claiming "that chronic pain affects more than 100 million Americans . . . . Prescription opioid medications are an important part of a treatment plan for people living with chronic pain." Matthew Day Dep. (01/04/19), Dkt. # 1961-11 at 239:4-240:4.

Defendants orchestrated a vast campaign to change the medical standard of care for prescription opioids. Their efforts were remarkably successful. Opioid prescribing tripled between the 1990s and 2012, with dramatic increases in the dosage prescribed and the duration of use. *See* Lembke Rep., Dkt. # 2000-10 at 10-11. "By 2010, enough [opioid pain relievers] were sold to medicate every American adult with a typical dose of 5 mg of hydrocodone every 4 hours for 1 month." *Id.* at 10. With this dramatic increase in supply, so followed the harms, with dramatic increases in opioid addiction and opioid-related deaths. In 2016, more than 17,000 people died from a prescription opioid overdose, up almost 400% from 3,442 deaths in 1999. Schumacher Rep., Dkt. # 2000-24 at 26. In all, the opioid epidemic Defendants created has claimed roughly 400,000 lives. *See* CDC, Understanding the Epidemic, available at https://www.cdc.gov/drugoverdose/epidemic/index.html (last accessed July 29, 2019).

[2] *See also* Ex. 154, Declaration of Roxann Montgomery ("It was up to the doctors to raise the risk [of addiction], and if they did, the mantra we were to convey was that the world was undertreating pain, and that the people deserving ample pain control were not getting it.")

Because of doctors' addiction fears, Defendants used multiple promotional and marketing approaches—all of which were unlawful and fraudulent—to persuade physicians and patients who expressed caution and concern. The record is replete with evidence that each of the Manufacturer Defendants minimized addiction risks by falsely claiming that its occurrence rate was "less than 1%" and the risk was "low" or "rare." *See, e.g.,* Report of Dr. Matthew Perri, Dkt. # 2000-21 at 86-137, Schedule 10 (compiling examples of misleading and false marketing statements by each Manufacturer Defendant); Lembke Rep., Dkt. # 2000-10 at App'x I (same); Schumacher Rep., Dkt. # 2000-24 at Exhibits A-C (same); Report of Dr. David A. Kessler, Dkt. # 2000-8 at 28-291 (same).

For example, Purdue repeatedly cited to a 1980 Letter to the Editor by Drs. Porter and Jick published in the New England Journal of Medicine for the claim that less than 1% of patients treated with opioids will become addicted. *See* Ex. 3, PKY180117076-7087 at 7086 (Porter and Jick letter should be used as support in telling doctors that risk of addiction "is extremely rare."). Purdue also created "Partners Against Pain," a pain advocacy group, to promote the misconception that the percentage of patients who might become addicted is "1%," citing again the Porter & Jick Letter. *See* Ex. 4, PKY180112501-2516 at 2511 ("Many patients—and family members—will be surprised to discover that fewer than 1% of opioid using patients become addicted!"). Similarly, Janssen's sales training materials used the letter to falsely claim that addiction "is exquisitely rare." Ex. 5, JAN-MS-00653426 at slide 25. Teva similarly referenced the Porter letter, stating that "addiction resulting from exposure to opioid therapy is uncommon. In one survey of patient [sic] taking opioids for severe chronic pain, only four of 11,882 patients developed addiction." *See* Ex. 112, TEVA_MDL_A_00890304-0382 at 0351.

But the Porter and Jick letter did not provide scientific support for that claim. Instead, it was not a study but merely a recitation of patients who received at least one dose of an opioid while under hospital care and supervision, and it contained no information about dose size, duration or the extent

of any long-term follow-up. Lembke Rep., Dkt. # 2000-10 at 14-15; Schumacher Rep., Dkt. # 2000-24 at 22; Kessler Rep., Dkt. # 2000-8 at 58. In other words, it provided no scientific data as to the addiction experience of patients on opioids long-term for chronic pain. *See also* Ex. 145, PLTF_2804_000003808-3844 at 3839 ("Portenoy Declaration" describing Porter & Jick letter as very limited and that it "should not have been used by the pharmaceutical industry to indicate the addiction rate associated with chronic pain treatment.")

Likewise, Endo represented that "addiction to opioids in the context of pain treatment is rare in those with no history of addictive disorders." Ex. 6, ENDO-OPIOID_MDL-01761737 at slide 33. Endo included no data to support that statement, admitting in its labeling submission to the FDA for Opana ER that "data are not available to establish the true incidence of addiction in chronic pain patients." Ex. 7, ENDO-OPIOID_MDL-00298948-9000 at 8962. Mallinckrodt trained its sales force to falsely convey that while "most" chronic opioid users might develop "tolerance and physical dependence," it was due to "medical reasons" not addiction because the "risk of addiction is low." Ex. 8, MNK-T1_0001161164-1237 at 1192. Allergan's sales training book for its opioid, Kadian, was rife with misinformation, including that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction," and that physicians required education to overcome their "inappropriate fear of addiction." Ex. 9, ALLERGAN_MDL_01052119-2465 at 2254; Ex. 10, ALLERGAN_MDL_01610522-0713 at 0552. Janssen distributed a patient booklet on Duragesic, which claimed that "[a]ddiction is relatively rare when patients take opioids appropriately," and "[p]hysical dependence is not the same as addiction. It is easily managed by gradually reducing the dose of the drug." *See* Ex. 146, JAN-MS-02757826-7857 at 7847.

Defendants also created front organizations to promote wider opioid use. Mallinckrodt, for example, funded a group called CARES Alliance, that disseminated "educational tools" for patients. Ex. 11, MNK-T1_0001493093-3105 at 3105. One such tool was called "Defeat Chronic Pain Now!"

Id. at 3099. It falsely stated that "[w]hen chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving." Ex. 12, Galer & Argoff, Defeat Chronic Pain Now! at 176 (2010). Janssen used an unbranded website, "prescriberesponsibly.com," to falsely claim that "true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid . . . therapy." Ex. 13, JAN-MS-03090610-0613 at 0611. Similarly, Teva's "Pain Matters" unbranded marketing campaign, in an "Evolving Roles, Same Goals and Video Script," states that addiction risk "is clearly greater in patients with a previous history of abuse or addiction and that it's relatively low for patients with chronic non-malignant pain who don't have a previous history of addiction." Ex. 113 TEVA_MDL_A_08652504-2532, at 2510. Endo fully funded and directed the National Initiative on Pain Control (NIPC), whose "Pain Action Guide" promised: "Pain medications rarely cause addiction…Unless you have a history of substance abuse, there is little risk of addiction when these medications are properly prescribed by a doctor and taken as directed." Ex. 147, CHI_000435580-5597 at 5588 (2000 edition); *see also* Ex. 148, CHI_000432477-2519 (same in 2003 edition).

Purdue—to control doctors' concerns about prescribing a long-acting opioid like OxyContin—falsely maintained that its time-released action reduced addiction risk as compared to immediate-release, short acting opioids. *See* Kessler Rep., Dkt. # 2000-8 at 50-58. But this marketing claim was never scientifically studied and Purdue eventually admitted as much. *Id.* at 46-48. Nonetheless, Purdue sales representatives were trained to instruct that "[d]elayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug." *Id.* at 50; Ex. 14, SHC-000006346-6353 at 6351. There is evidence that this misrepresentation was repeated by the sales representatives in visits to Ohio doctors. For example, a call note dated November 7, 1997 states:

> ALWAYS RELUCTANT TO USE NARCS BUT TOLD IF GOING TO PUT PT ON VIC/LORT OR TYL 3, WHY NOT USE THE 12 HR DOSED [sic], WITHOUT TYLENOL AND LESS ABUSE POTENTIAL.

Ex. 15, PPLPMDL0080000001, at row 76265. As one sales representative in Ohio put it, the "low abuse" pitch for OxyContin to doctors previously prescribing Vicodin was "easy money." Ex. 16, PPLPMDL0080000001, at row 98319.

Defendants also used paid-for "thought leaders" like Dr. Russell Portenoy, to push the narrative that addiction risks were minimal:

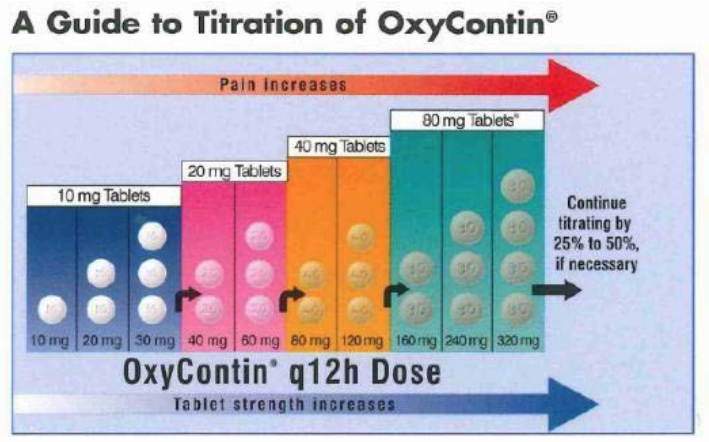
> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite. I would cite 6 to 7 maybe 10 different avenues of thought or evidence, none of which represents real evidence. And yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in toto and feel more comfortable about opioids in a way they hadn't before. . . . Because the primary goal was to de-stigmatize, we often left evidence behind.

Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), available at, https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be. (last accessed July 24, 2019); *see also* Ex. 145, PLTF_2804_000003808-3844 at 3837 ("Portenoy Declaration" stating "I believe that drug companies used my work to provide content and expert support for a strongly positive message about opioids, and in much of the material produced by drug companies, the content lacked context and warnings, and in so doing, presented a message that lacked balance. The effect was to promote opioid therapy to prescribers.").

Contrary to each Defendant's marketing, there has never been scientific support for the claim that the risk of addiction is "rare," or "less than 1%." *See* Lembke Rep., Dkt. # 2000-10 at 5. Despite its false marketing claims, Purdue acknowledged as much, stating in 2001 that, "there are no data to accurately characterize the extent of addiction" among patients taking opioids. Ex. 17, SHC-00020630-0639 at 0104. In fact, the scientific evidence demonstrates that the risk of addiction from chronic opioid therapy is between 10% and 29%. *See* Lembke Rep., Dkt. # 2000-10 at 5.

Defendants also inaccurately promoted opioids as safe to use at increasing dose levels. This too was false. Increasing the dose increases the risk of addiction as well as the adverse effects from

addiction, including overdose and death. *Id.* at 5. The Manufacturer Defendants misleadingly represented that their "new" pure opioids could be safely used at high dose levels and there was no ceiling on safety. *Id.* at 63. Plaintiffs' experts cite many examples of such claims. For example, a Purdue 2003 OxyContin conversion guide indicates there is no dose limit for treating pain:



Ex. 18, PDD1501128421-8476 at 8455.

Janssen in 2011 told doctors prescribing Nucynta "you may titrate your patients at your discretion, based on your assessment of their pain management needs." Ex. 19, JAN-MS-00016372-6397 at 6380; *see also* Ex. 20, JAN-MS-00653403 at slide 26 ("no ceiling dose for opioids"). Similarly, a 2004 brochure from Endo told patients worried that their opioid might stop working that "it is not a problem" because the "dose can be increased or other medicines can be added." Ex. 21, ENDO-CHI_LIT-00084049-4056 at 4052. Allergan's message was the same, telling patients whose bodies became "tolerant" at their current dose that "[t]his is not addiction," but rather a "dose adjustment" was required. Ex. 22, ACTAVIS0006823-6830 at 6826. Mallinckrodt used a song to deliver the same false message to its sales representatives, telling them, "make sure you just don't stop" increasing the dose of Exalgo "[c]ause your patient needs relief, mon." Ex. 23, MNK-T1_0004166098-6100 at 6098-99.

There is no doubt that the "no dose limit" message reached Ohio. For example, a Purdue sales representative logged the following communication with an Ohio physician in 2000:

> SPOKE WITH MD WHO EXPRESSED CONCERN RE: ONE PT RECEIVING 120 MG Q 12 FOR BACK PAIN-**DISCUSSED THE PFACT [sic] THAT THERE IS NO CEILING DOSE WITH OXY** LIKE SHORT ACTING; HE SEEMED TO THINK THAT THIS PT WAS ABUSING THE PRODUCT; HE NEEDS REAFFIRMATION RE: THE DECREASED ABILITY OF OXY TO BE ABUSED AND DECREASING NUMBER OF TABS….

Ex. 24, PPLPMDL0080000001 at row 170276 (emphasis added); Ex. 25, PLPMDL0080000001 at row 202957 (Ohio doctor told "there is no ceiling" for OxyContin and "he should not worry about how high he needs to go.").

It was demonstrably false for the Manufacturer Defendants to promote "no dose" ceiling and safety at higher doses. The higher the dose, the higher the risk of death; this risk may occur for some patients at doses that were even previously thought to be safe. *See* Dasgupta, N., et al., *Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality*, Pain Med, 2016, 17(1) pp. 85-98; Dunn, K.M., et al., *Opioid Prescriptions for Chronic Pain and Overdose: a Cohort Study*, Ann Intern Med, 2010. 152(2): pp. 85-92 (compared with 1 to 20 mg/d, patients receiving 50 to 99 mg/d of opioids had a 3.7-fold increase in overdose risk and patients receiving 100 mg/d had an 8.9 fold increased risk); *see also* Lembke Rep., Dkt. # 2000-10 at 15, 63-66; Schumacher Rep., Dkt. # 2000-24 at 37-38.

An additional marketing tactic to conceal the true addictive nature of opioids was to describe addictive symptoms as "pseudoaddiction" that required more opioids, not fewer. For example, Endo's front group, NIPC, disseminated "pain education" to prescribers that defined "pseudoaddiction" as "behaviors that might seem aberrant, but actually indicate inadequate treatment of pain" which will resolve "when the pain medication is increased and appropriate analgesia is obtained." Ex. 26, ENDO-OPIOID_MDL-01605952-5958 at 5955. Mallinckrodt's CARES Alliance distributed brochures that claimed pseudoaddiction was a legitimate medical condition when no such evidence existed. *See* Ex. 27, MNK-T1_000097450-7467 at 7454; *see also* Ex. 28, MNK-T1_0001492929 at slide 63

("Pseudoaddiction: Patients who are receiving an inadequate dose of opioid medications and seek more."). Allergan taught its sales force that pseudoaddiction reflected "not signs of substance abuse, but rather should be considered symptoms of inadequate treatment." Ex. 29, ALLERGAN_MDL_00439499-9855 at 9532. A Janssen marketing document told doctors "[p]atients who watch the clock or know just when the next medication dose is due are likely to be suffering from undertreated pain, not addiction." Ex. 30, JAN-MS-02268552-8561 at 8555. These messages certainly were delivered to the Plaintiff Counties by Defendants' sales representatives. *See* Kessler Rep., Dkt. # 2000-8 (detailing call notes); Perri Rep., Dkt. # 2000-19 at 95-101.

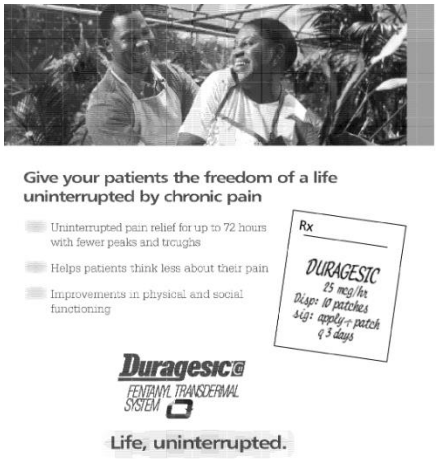
Purdue's Partners Against Pain promoted, among other claims, that clock watching and other inappropriate "drug seeking," was just patients with undertreated pain, i.e., "pseudoaddiction." Ex. 32, PPLP004114967-4991 at 4970. For its part, Teva, in a 2008 "Introduction to Pain" educational "Pre-module" booklet misleadingly stated that, "[i]f patients receive inadequate pain relief, they may exhibit drug-seeking behaviors. This is called pseudoaddiction." Ex. 112, TEVA_MDL_A_00890304-0382 at 0355.

Pseudoaddiction is not a scientifically valid concept and had the intended effect of encouraging doctors to ignore signs of addiction, and instead respond with more opioids—the most dangerous response. *See, e.g.,* Kessler Rep., Dkt. # 2000-8 at 62-63 ("Pseudoaddiction is not supported by substantial evidence"); Lembke Rep., Dkt. # 2000-10 at 5 ("There is no such thing as 'pseudoaddiction'"); Ex. 33, ENDO-OPIOID_MDL-01463855-4070 at 3956 (APS and AAPM finding no studies on accuracy of "tools for differentiating" opioid addiction from pseudoaddiction exist in the literature).

2. The Manufacturer Defendants' Marketing Campaign Overstated the Benefits of Prescription Opioids for Long-Term Use.

There is also evidence that each Manufacturer Defendant's marketing and promotion overstated the benefits of opioids for long-term use without scientific support for such statements. Patients were told that their health, function, and quality of life would improve from opioid use:

Ex. 34, PDD1501614879-4901 at 4881-4882.



Ex. 35, JAN-MS-00306286-6293 at 6293.

The impression from this type of material was that "opioids are safe and effective, seldom harmful, and usually beneficial." Schumacher Rep., Dkt. # 2000-24 at 39. All Manufacturer Defendants participated in painting this picture. The expert reports are replete with examples of such

promotional claims. For example, Purdue's Jim Lang recommended that sales representatives tell doctors that "OxyContin can provide pain relief to your patients, allowing them to sleep through the night, while potentially creating less chances for addiction than immediate-release opioids." Ex. 36, SHC-000003754-3756 at 3755. The FDA had told Purdue this type of claim "would be misleading because it fails to disclose that these improvements were in comparison to placebo only." Ex. 37, PURCCHI-000623100-3102 at 3101. Despite the FDA's caution, Purdue's sales representatives told Ohio's doctors that OxyContin was proven to improve a patient's quality of life as compared to other opioid products. *See* Ex. 38, PPLPMDL0080000001 at row 86767 ("DR USES PERCODAN, HIT OXY WITH DELIVER SYSTEM, LESS FREQUE[N]T DOSING, IDEA OF IMPROVEMENT IN QUALITY OF LIFE . . ."); Kessler Rep., Dkt. # 2000-8 at 89-94 (providing specific examples of misleading detailing in Ohio).

A Janssen document aimed at "older adults" stated it was a "myth" that opioids "make it harder to function normally" when in fact they "may make it easier . . . ." Ex. 39, JAN-MS-00476773-6793 at 6782. Likewise, a Mallinckrodt sales representative pushed the message that extended opioids allow patients "to get more sustained relief allowing them to lead a more productive life." Ex. 40, MNK-TI_0002157893-7894 at 7893. But there was no scientific basis for these statements and scientific evidence has emerged that long-term opioid use actually decreases function or quality of life. A Danish study, Erikson et al. (2006), found that "opioid usage was significantly associated with reporting of moderate/severe or very severe pain, poor self-rated health, not being engaged in employment, higher use of the health care system, and a negative influence on quality of life." Schumacher Rep., Dkt. # 2000-24 at 40; *see also* Lembke Rep., Dkt. # 2000-10 at 21-37.

Other misleading "benefits" promoted by the Manufacturer Defendants included that opioids could be prescribed for any age group without risk and were safer and more effective than alternative treatments, such as NSAIDs. For example, Allergan's marketing claimed that "[m]aintenance therapy

with opioids can be safer than the long term use of other analgesics, such as Cox-2 inhibitors, nonselective NSAIDS, or acetaminophen . . . .” Ex. 41, ALLERGAN_MDL_01741588-1639 at 1598. Also, to convince doctors to expand their use of opioid prescriptions, the Manufacturer Defendants promoted their use as first line treatment for any type of pain. Teva’s 2003 Marketing Plan for Actiq contemplated using “KOLs in the field of pain management” to “gain the exposure and support needed to become a first line treatment option for BTP [breakthrough pain].” Ex. 42, TEVA_CHI_00042951-3009 at 2982; *see also* Ex. 114, TEVA_MDL_A_ 01399742-9750 at 9746, (brochure entitled “Breakthrough Pain: Do you still have pain?” stating “Get Rid of Common Myths About Pain: … Concerns about addiction should NOT prevent proper pain management.”). Purdue’s slogans for OxyContin included: “OxyContin-The one to start with.” Ex. 43, PURCHI-000622986-3094 at 3050. The scientific evidence is contrary: “[c]ompared with other commonly used pain relievers such as non-steroidal anti-inflammatory drugs (NSAIDs), the health and addiction consequences are substantially and significantly greater from opioids than from NSAIDs, including for cardiovascular events, fractures, and falls, as well as poisoning and overdose.” Report of Dr. Katherine Keyes, Dkt. # 2000-9 at 3.

More cynically, the Manufacturer Defendants’ marketing included threats that failure to prescribe opioids would lead to the under treatment of pain and perhaps even constitute malpractice. Endo’s promotional materials in 2006 claimed that “[u]ndertreatment of pain produces economic and social costs over tens of billions of dollars each year in the U.S . . . . Opioids have been proven to treat chronic pain effectively and thus can help eliminate undertreatment, if used properly.” Ex. 44, ENDO-OPIOID_MDL-02150882-0941, at 0888. Likewise, pushing the idea that “[u]ndertreatment of pain is a serious problem in the United Sates,” Purdue promoted opioids as an “important aspect of quality medical care” and “often the only treatment option that provides significant relief.” Ex. 45, PPLP003516982-6997 at 6985; *see also* Ex. 46, PKY181728376-8445 at 8398 (“The undertreatment of

pain in today's society is not justified"); Ex. 47, Acquired_Actavis_00943445 at slide 3 ("[U]ndertreatment of chronic pain is a serious public health issue that results in enormous social cost . . . .").

According to the Manufacturer Defendants' promotions, leaving pain undertreated was riskier than using opioids. Endo claimed that "[c]hronic pain disables more people than cancer or heart disease and costs the American people more than both combined." Ex. 48, END00366720-6757 at 6722. Purdue was even more dramatic, claiming in 2007 that "[t]he consequences of untreated or undertreated pain are profound—physically, psychologically, spiritually, as well as economically." Ex. 49, PPLP004058784-8815 at 8804. But these marketing statements were false. Actavis received a warning letter from the FDA for circulating a brochure to patients for Kadian representing that pain "can keep you from enjoying life" and "[i]f left untreated, pain can place stress on your body and your mental health. . . ." Ex. 50, ACTAVIS0238310-8322 at 8319. The FDA found that these representations constituted unsubstantiated claims of effectiveness, as it was "not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviated pain, taken together with any drug-related side effects patients may experience . . . results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or the enjoyment of life." *Id.* at 8320. These intentional promotional activities "contributed to the rising incidence of drug addiction and overdoses." Ex. 145, Declaration of Dr. Russell Portenoy, PLTF_2804_000003808-3844 at 3811, 3843.

As Dr. Lembke opines, "there is not, and has never been, reliable evidence that long-term opioid use improves pain or function to any clinically meaningful degree." Lembke Rep., Dkt. # 2000-10 at 21. These misconceptions promoted by Defendants about the risks and benefits of opioids "were the single most significant factor giving rise to the massive increase in the sale of opioids and the resulting epidemic of dependence and addiction . . ." *Id.* at 75.

3. The Manufacturer Defendants Expanded the Use of Opioids by Infiltrating Pain Advocacy Groups and Professional Medical Organizations.

To expand the prescribing of opioids for chronic conditions, Manufacturer Defendants went to great lengths to infiltrate pain advocacy and professional medical organizations. *See* Kessler Rep., Dkt. # 2000-8 at 295-313. The American Pain Society ("APS"), in return for millions of dollars of funding from Purdue, Janssen, Endo, Mallinckrodt, and Teva, allowed opioid manufacturers to sit on its guideline committee and provide input. *See* Ex. 51, ENDO-OPIOID_MDL-06234663; Ex. 52, PKY181215547-5749 at 5560; Ex. 53 PKY181775488-5494. Purdue, Janssen, and Mallinckrodt also made millions of dollars in contributions to the American Academy of Pain Medicine (AAPM)—an organization whose mission was to educate and train physicians about pain treatment. Kessler Rep., Dkt. # 2000-8 at 303. In 1997, APS and AAPM issued joint guidelines for "The Use of Opioids in Chronic Pain" that included many misleading statements, including that "development of addiction when opioids are used for the relief of pain is low;" "for most opioids, there does not appear to be an arbitrary upper dosage limit;" and "undertreatment of pain in today's society is not justified." Ex. 54, PPLPC051000030818-0821 at 0819, 0821. Guidelines such as these were then used by the Manufacturer Defendants in their marketing. *See* Ex. 55, JAN-MS-00303825 at 2 ("[S]tudies indicate that the de novo development of addiction when opioids are used for the relief of pain is low," referencing Definitions Related to the Use of Opioids for the Treatment of Pain: A Consensus Document from the AAPM and APS).

AAPM Executive Director Dr. Barry Cole had a particularly close relationship with Purdue and felt he could be "more helpful to the Company by remaining a third party—unencumbered by FDA guidelines for what he can say about our products or the class of drug." Ex. 56, PDD8801104393. By "flying under the umbrella of American Academy of Pain Management," Purdue's Robin Hogen wrote, Dr. Cole "has tremendous credibility and cannot be discounted as a

company flak." *Id.* Dr. Cole's help to Purdue extended to Ohio, where he bragged in a 2001 email to Purdue's Dr. Reder that his three conversations with a Cleveland Free Times reporter had resulted in "some articles and letters" that were "all very supportive of OxyContin." Ex. 57, PPLPC029000042442-2443 at 2443.

Another co-opted group was the American Pain Foundation ("APF"), which was founded in 1997 as "the nation's leading independent nonprofit organization serving people with pain." APF published materials that used the same misleading promotional messages about the benefits and risks as the opioid Manufacturers did in theirs. APF's Board included members who were paid consultants to Purdue and Janssen. *See* Kessler Rep., Dkt. # 2000-8 at 305. Before it ceased operation in 2012, APF had already received contributions from Purdue, Mallinckrodt, Janssen, and Endo totaling in the millions of dollars. *See* Kessler Rep., Dkt. # 2000-8 at 305-306. As Purdue's Robin Hogen put it, "if they want our bucks (and they honestly connot [sic] survive without industry support) they are going to have to learn to live with 'industry' reps on their board. I don't think they can expect huge grants without some say in governance." Ex. 58, PPLPC025000012558-2559 at 2558.

Pain groups funded by the Manufacturer Defendants also worked to increase access to opioids and limit regulatory scrutiny of doctors prescribing them. One such advocacy group was "Ohio Pain Initiative," or "OPI." Purdue frequently met with OPI members to "discuss partnering opportunities" and to discuss "several ways in which [OPI] membership could be increased." Ex. 59, PKY182755104-5121 at 5116. Purdue, Janssen, and other Manufacturer Defendants funded various OPI research literature, some of which pushed the concept that wariness of prescribing powerful painkillers was unjustified. *See* Ex. 60, ENDO-OPIOID_MDL-03646475-6480 at 6478, Ex. 61, PPLPC024000087261-7263; Ex. 62, JAN-MS-01195347-5348. Individual high ranking OPI members had personal and financial ties with Manufacturer Defendants, acting as paid speakers, consultants, or KOLs. *See, e.g.,* Ex. 63, JAN-MS-03021928 at 9-10 (OPI President, Warren Wheeler); Ex. 64,

PKY180771362; (OPI Treasurer, Debra Heidrich); Ex. 65, PPLPC013000291329 (OPI Board Member, Steven Stanos).

OPI also participated in multiple instances of lobbying Ohio governmental officials and also attempted to influence legislation regarding opioids. One such instance of legislation was the Compassionate Care Bill (House Bill 474), which created "The Ohio Compassionate Care Task Force." Ex. 66, PPLPC022000021468. Purdue paid, and also employed the assistance of, Task Force board members who disseminated messages that prescribing of opioids in Ohio was "timid" and "inadequate" because doctors feared disciplinary action, civil lawsuits, or criminal prosecution. Ex. 67, PPLPC023000040965-0967; Ex 68, PPLPC018000049757 at 8 (Task Force member Eric Chevlen). Defendants made these and similar misrepresentations to the Pharmacy and Therapeutics Committee, which determined which medications appeared on the Ohio Department of Medicaid's Preferred Drug List. Ex. 69, Deposition of Mary Applegate at 330:17-336:23; Ex. 70, Deposition of Donald Wharton at 353:21-355:4.

Another example is the University of Wisconsin Pain and Policy Study Group (PPSG) and its director, David Joranson. PPSG's goals included "work to identify and address regulatory barriers to pain management" in order to "achieve more balanced opioid regulation and improved availability of opioid analgesics." Lembke Rep., Dkt. # 2000-10 at App'x II, p. 1. PPSG's efforts included removing restrictions in Ohio, and encouraging the adoption of an Intractable Pain Law, Ohio Admin Code § 4731-21, a bill that promoted opioid prescribing by shielding doctors from disciplinary action if the opioids were prescribed in compliance with the terms of law. Lembke Rep., Dkt. # 2000-10 at 33. PPSG documents described Ohio as one of 16 states with "improved pain policies" between 2000-2003. Ex. 71, WIS_PPSG_000703 at slide 18. PPSG received millions of dollars in financial support from the Defendants, including Purdue, Endo, Allergan/Actavis and Janssen. Lembke Rep., Dkt. # 2000-10 at App'x II, p.5. As PPSG director Joranson wrote to Purdue's Robert Kaiko in 2002,

"[w]ithout your support, some of the progress reported below would not have been possible." Ex. 72, WIS_PPSG_006457 at 1. He then asked for an additional grant of $175,000, renewable for two years. *Id.*; *see also* Lembke Rep., Dkt. # 2000-10 at App'x II (setting forth evidence regarding Defendants' funding of PPSG and PPSG efforts to expand use of opioids).

Defendants' support of pain advocacy groups and professional medical organizations was significant. The extensive payments made to these groups by the Manufacturer Defendants are described in great detail in Dr. Perri's expert report. *See* Perri Rep., Dkt. # 2000-21 at Schedule 17; *see also id.* at 41, 45 ("Working with these groups was an integral part of Defendants' marketing" and allowed the Defendants "to more widely disseminate their marketing messages, which had the added benefit of appearing to be unbiased . . . ."). It was also highly irresponsible. As Joel Saper, committee member of some these pain organizations, observed, "advocacy for [opioids] has to be based on medical common sense independent of the financial flow of dollars, and it was my growing fear that that was not the case in the case of these guidelines and programming within the various organizations." *See* Joel Saper Dep. (01/11/19), Dkt. # 1970-15 at 45:7-22. But the support of these groups had its intended effect — as Dr. Kessler opines, "the opioid manufacturers support for and involvement" with these groups "contributed to altering the standard of care for the treatment of pain by encouraging healthcare providers to view pain as a 'fifth vital sign' that demanded aggressive treatment with opioids." Kessler Rep., Dkt. # 2000-8 at 295-296. That, in turn, "expanded the use of opioids and increased the risk of addiction[,] abuse, overdose and death." *Id.* at 296.

B. THERE IS EXTENSIVE EVIDENCE THAT DEFENDANTS COLLECTIVELY, AND EACH DEFENDANT SEPARATELY, DID NOT MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION OF PRESCRIPTION OPIOIDS.

Defendants were obligated to prevent diversion. As shown in Plaintiffs' Memorandum in Support of Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties Under the Controlled Substances Act (Dkt. 1887), manufacturers, distributors, and pharmacies are required to

design and operate systems (also known as suspicious order monitoring systems ("SOM")) to identify suspicious orders, to report such orders to the DEA, and to refrain from shipping such orders unless and until they confirm that the orders are not likely to be diverted. *See* 21 U.S.C. §§ 801 *et seq*.; 21 C.F.R. 1301 *et seq*. Substantial and undisputed evidence here shows that each Defendant blatantly failed, at every level, to comply with these duties. This evidence includes Defendants' internal documents concerning their SOM programs, Defendants' communications with the DEA, and Plaintiffs' expert reports analyzing the Defendants' SOM programs and their lack of compliance with the CSA. *See* Plaintiffs' Memorandum of Law In Support of Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties Under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them (Corrected) (Dkt. 1924).

Several Manufacturer Defendants *themselves* have already publicly and privately admitted to failing to comply with CSA suspicious order monitoring requirements. Mallinckrodt, for example, in a 2017 agreement with the U.S. Department of Justice and the Drug Enforcement Administration, admitted that it failed to maintain effective controls against diversion. *See* Ex. 73, Administrative Memorandum of Agreement between U.S. DOJ, DEA and Mallinckrodt (July 10, 2017); *see also* Karen Harper Dep. (01/15/19), Dkt. # 1962-19 at 199:24-200:10 (admitting that Mallinckrodt "did not always perform due diligence on peculiar orders before shipping them."). Similarly, Qualitest, acquired by Endo in 2010, admitted that its SOM program was "[i]nadequate[.]" Tracey Norton Dep. (01/16/19), Dkt # 1968-21 at 378:12-380:9, 387:14-388:3. At Actavis, employees warned that their monitoring process was inadequate to "prevent shipping excess product," Ex. 74, ALLERGAN_MDL_02128035-8036. And, in 2015, Teva's parent company in Israel, Teva Pharmaceuticals Industries Ltd., audited Teva's DEA compliance department and found that their DEA Department was in "noncompliance with DEA requirements." Ex. 75, TEVA_MDL_A_02475565-5585 at 5569.

For many Manufacturer Defendants, there were few, if any suspicious order monitoring policies in place at all during certain time periods. For example, as of September 2012, Teva had never had a written suspicious order monitoring system in place and had never reported a suspicious order to the DEA. Ex. 76, TEVA_MDL_A_01060005-0012 at 0005, 0007. Internal Purdue documents reveal that it would only receive data "that is a month old," and that any review "would be well after the shipment . . ." Ex. 77, PDD8801146346-6347 at 6346. Purdue's Vice President and Chief Security Officer could recall only one instance in which an order was cut or blocked due to size, frequency or pattern. *See* Mark Geraci Dep. (04/04/19), Dkt. # 1962-8 at 222:11-226:13. A 2016 audit of Purdue's Suspicious Order Monitoring System produced devastating results. BuzzeoPDMA, hired by Purdue's outside attorneys, conducted the audit and found that Purdue's monitoring system was divorced from DEA's definition of "suspicious orders," used arbitrary thresholds, did not conduct due diligence on customer behaviors with respect to opioids and put review of pending orders in the hands of entities that had sales and marketing as their core mission. *See* Ex. 149, PPLP004510993-1006. From 2008-2009, Mallinckrodt had no suspicious order program in place at all, aside from verifying that the customer had valid DEA 222 forms; even before and after that, Mallinckrodt had no mechanism in place to halt suspicious orders. *See* James Rausch Dep. (11/16/18), Dkt. # 1970-3 at 139:14-140:9; *see also* Ex. 150, MNK-T1_0000300799 ("we do not do anything with these orders except . . . to release them"). And, an outside audit determined that Endo Defendant "Par" had no SOM program whatsoever in 2010. *See* Stephen Macrides Dep. (03/15/19), Dkt. # 1966-11 at 164:9-166:16.

But even when Manufacturer Defendants had SOM systems in place, they were remarkably ineffective. For example, many Manufacturer Defendants had programs utilizing various rigid numeric formulas that flagged orders if they exceeded the average (or multiples of the average) of previous orders for a given time period. *See* Report of Dr. James Rafalski, Dkt. # 2000-22 at 151-186. However, as the DEA and Defendants themselves have observed, these programs failed to identify orders of

unusual frequency or outside of the normal pattern, did not incorporate observational or charge-back data, were based on inflated baselines of sales measured when opioids already were dramatically oversupplied, and were unable to flag orders that consisted of gradual quantity increases over time or orders for controlled substances which initially commenced with larger than normal quantities and remained at a constant. *See* Ex. 78, MNK-T1-0007146632-6633; John Gillies Dep. (02/07/19), Dkt. # 1962-10 at 74:17-23. Janssen's SOM algorithm was also materially deficient in that it was narrowly designed such that an order would only be compared to previous orders *of the same product at the same strength*. *See* Michele Dempsey Dep. (01/22/19), Dkt. # 1962-12 at 144:22-148:10. Other Defendants, such as Qualitest, had their own sales department set the threshold amounts and authorized them to increase the threshold if requested by the customer. Norton Dep., Dkt. # 1968-21 at 289:19 – 290:6, 297:2-4. Often, these salespeople would modify large orders by dividing them into several smaller orders to ensure each modified order cleared their thresholds. Ex. 79, PAR_OPIOID_MDL_0000398174-8191 at 8177 ("the size of the order was cut down and the order was approved . . .").

Finally, even if Manufacturer Defendants' systems managed to flag a suspicious order, Defendants rarely stopped or reported the order, as required under CSA guidelines. Mallinckrodt, for example, placed its salesforce in key roles for the investigation and clearing of suspicious orders. *See* Harper Dep., Dkt. # 1962-19 at 59:13-19. Like Mallinckrodt, Teva kept the key investigatory role in the hands of its sales department. Ex. 80, TEVA_MDL_A_02660892-0899. Also unsurprisingly, a 2015 audit determined that Teva investigated 10,000 line orders per month of Schedule II products; 95% were automatically released. *See* Ex. 75, TEVA_MDL_A_0275565-5585 at 5570. For its part, Endo placed its customer service division in charge of clearing suspected orders. *See* Lisa Walker Dep. (12/04/18), Dkt. # 1971-20 at 42:24-43:18. Endo's Director of Distribution and Customer Service testified that in the twenty years she has been at Endo, she does not recall *a single order* being stopped

by her team. *Id.* at 54:12-18, 63:16-65:20. Endo has also *never reported a suspicious order* to the DEA. *Id.* at 55:5-11. And Actavis Defendant, Watson, allowed orders to be shipped based on "an employee inside of the company [including salespeople] providing the justification" in "an email." Ex. 81, Deposition of Mary Woods at 140:3-141:9.

Manufacturer Defendants' failures to maintain adequate controls against diversion are particularly egregious in light of the detailed transactional sales information they possessed or could access. For example, Mallinckrodt and Endo had access to "charge-back data"[3] regarding where their products were going, but failed to adequately utilize this data. Harper Dep., Dkt. # 1962-19 at 360:11-365:10; Walker Dep., Dkt # 1971-20 at 162:23-163:24, 175:6-21, 190:1-5, 635:1-7, 647:23-648:1. At the very least, use of this data would have revealed that many pharmacies and pain clinics were purchasing opioids from multiple distributors, which is a red flag for diversion. *See* Ginger Collier Dep. (01/08/19), Dkt. # 1961-4 at 197:6-11; Rafalski Rep., Dkt. # 2000-22 at 147; Keller Rep., Dkt. # 2000-7 at 99. Janssen, in turn, had access to transactional sales data, including charge-back data, wholesalers' inventory and sales data, and third-party data from Integrichain and ValueTrak. *See* Rafalski Rep., Dkt. # 2000-22 at 161. While their sales and marketing teams extensively utilized this type of data for sales and to target high-volume prescribers, Defendants failed to incorporate any of this sales data to monitor suspicious prescribers. *Id.*

Distributor and Pharmacy Defendants' dereliction of their CSA duties was equally, if not more staggering.[4] As with the Manufacturer Defendants, one need only look as far as their own public admissions as well as the numerous DEA investigations conducted against them. Cardinal, for example, admitted in its May 2012 agreement with the DEA "that its due diligence efforts for some

[3] "Chargeback data" is transaction information provided by Distributors to Manufacturers which allows manufacturers to determine who purchased its drugs, in what volumes, and in which doses. *See* Rafalski Rep., Dkt. # 2000-22 at 147.
[4] The evidence related to the Small Distributors' misconduct is set forth in Plaintiffs' Memorandum in Opposition to Non-RICO Small Distributors' Motion for Summary Judgment Based on Their De Minimis Status (PSJ9), and is incorporated herein by reference.

pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate." Ex. 115, CAH_MDL2804_02465982-6053 at 5984. Cardinal had also been issued numerous DEA suspension orders in 2007 and 2008 as a result of its lax anti-diversion practices, resulting in another 2008 settlement. *See* Ex. 126, CAH_MDL_PRIORPROD_DEA12_00013056-3103. Similarly, in a January 2017 settlement with the DEA, McKesson acknowledged that from 2009-2017 "it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious . . ." Ex. 116, MCKMDL00355349-5415 at 5352. This came less than a decade after DEA and DOJ, in 2008, punished McKesson for its flagrant noncompliance with the CSA. *See* Ex. 127, MCKMDL00337001-1071. Walgreens, as part of a settlement with DEA in June 2013, admitted that its "suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator . . ." Ex. 117, WAGMDL00490963-0978 at 0964. Walgreens had been issued show-cause orders and warrants in 2012 and 2013 for egregious misconduct. *See* Ex. 129, WAGMDL00387653-7707 at 7654; Ex. 130, WAGMDL00493694-3696. CVS also acknowledged, in two separate settlements with DEA, that it failed to meet its compliance obligations under the CSA. *See* Ex 118, CVS-MDLT1-000060805-0811; Ex 119, CVS-MDLT1-000060796-0804. AmerisourceBergen, too, was subject to DEA enforcement actions for its filling and shipping of orders of controlled substances ABDC knew, or should have known, to be suspicious. *See* Ex. 128, ABDCMDL00269383-9387. And, Defendant HBC entered into a settlement agreement with the Ohio State Board of Pharmacy in 2011 based on allegations that it had "failed to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs." Ex. 120, Deposition of Anthony Mollica, 90:10-95:17; 101:6-25; 202:7-16.

Distributor and Pharmacy Defendants' public admissions are corroborated by an examination of their actual diversion practices and policies. It is undisputed, for example, that Cardinal did not

have a policy to stop shipment of suspicious orders at all until 2008, and from 2008-2011, it reported only a few dozen suspicious orders per year, nationwide. *See* Ex. 121, CAH_MDL2804_03262274-2520 at 2438. One former sales supervisor swore in a declaration that Cardinal sales representatives coached customers to circumvent thresholds and that the "top sales representatives routinely broke rules to increase sales, and sales management often turned a blind eye or even encouraged the behavior." Ex. 155, Declaration of Kirk Klaasesz. McKesson had a policy in place from 1997-2007, though its own employees have acknowledged that this system did not flag true suspicious orders. Ex. 122, MCKMDL00510747-0752 at 0747; Gary Hilliard Dep., (01/10/19), Dkt. # 1963-1 at 176:8-176:22. Even when McKesson implemented new "threshold" measures in 2008, they were either set far too high to ever be triggered, or were increased without adequate justification from customers. *See* Ex. 123, MCKMDL00507799; Ex. 124, MCKMDL00633455. AmerisourceBergen's pre-2007 policy entailed shipping all orders of controlled substances it identified as suspicious *before* a due diligence investigation had ever occurred. Eric Cherveny Dep. (11/09/18), Dkt. # 1959-22 at 281:14-282:8. And prior to 2011, Walmart neither developed, nor maintained a suspicious order monitoring system. *See* Jeff Abernathy Dep. (11/15/18), Dkt. # 1956-1 at 42:23-43:5. Prescription Supply, Inc. never once reported a suspicious order, nationwide, from at least 2013-2017. James Schoen Dep. (02/27/19), Dkt. # 1970-16 at 115:19-116:2. Similarly, Rite-Aid reported zero suspicious orders, nationwide, from 1995-2014. *See* Janet Hart Dep. (1/30/19), Dkt. # 1962-21 at 114:4-8. HBC did not have a written SOMS policy at all until 2014, the same year it stopped selling controlled substances. *See* Ex 125, HBC_MDL00133445-3463. Pharmacy Warehouse Supervisor for Defendant DDM testified that she has never seen written policies or procedures regarding suspicious order monitoring and has never reported a single suspicious order to the DEA nationwide. Jill Strang Dep. (01/03/19), Dkt. # 1971-5 at 109:15-22; 315:13-317:3

As Plaintiffs' corporate compliance expert, Dr. Whitelaw, opines, prior to having pressure placed upon them by the DEA, the three big distributors—which account for 85% of the national drug supply—made only "token efforts to implement a compliance program to detect and prevent the shipment of prescription opioid products into an illicit market. . . ." Report of Dr. Seth Whitelaw, Dkt. # 2000-26 at 45. Even after DEA actions, "[c]ustomer relationship simply trumped compliance." *Id.* Same for the Pharmacy Defendants. Despite having "ready access to their own dispensing data, none of them tried to incorporate that information into their anti-diversion programs." *Id.* at 46. Rather, the evidence Dr. Whitelaw reviewed revealed that the pharmacies "invested substantial time and resources trying not to classify excessive pharmacy orders as 'suspicious,' so as not to disrupt product supply," and ultimately "profits." *Id.* The bottom line is that Manufacturer, Distributor, and Pharmacy Defendants did not want to identify, report, or stop shipping suspicious orders in compliance with the CSA. Instead, the overwhelming evidence demonstrates that they intentionally buried their heads in the sand while their opioid products poured into Plaintiffs' communities and they made billions.

C. PLAINTIFFS' ECONOMIC EXPERTS PROVIDE EVIDENCE OF CAUSATION OF HARM AND DAMAGES BY MARKETING CONDUCT.

Plaintiffs designated and provided reports from four economic experts: Doctors Meredith Rosenthal, Jonathan Gruber, David Cutler, and Thomas McGuire. The reports are inter-related and together provide important evidence to quantify causation and damages. Together, the reports of the economists show how unlawful marketing caused increased sales of opioids, how increased shipments

of opioids caused increased harms in Summit and Cuyahoga Counties, and how increased harms in those Counties caused the existing public nuisance and damages in Summit and Cuyahoga Counties.[5]

1. Dr. Rosenthal: Marketing Caused Increased Sales.

Dr. Rosenthal is a highly-credentialed Professor of Health Economics and Policy at the T.H. Chan School of Public Health at Harvard University, where she teaches undergraduate, masters, and Ph.D.-level health economics and policy courses. *See* Report of Dr. Meredith Rosenthal, Dkt. # 2000-23 at 1.[6] Dr. Rosenthal quantifies the effect of unlawful Manufacturer marketing on increased use of opioids in Summit and Cuyahoga Counties. She concludes that promotion of opioids increased sales of opioids. *Id.* at 8, 33-61. She also uses econometric modeling to quantify the extent to which increased sales of prescription opioids were caused by Defendants' unlawful marketing. *Id.* She performs this analysis for all Defendants' promotions, *id.* at 50-51, and separately for promotions with each individual Defendant excluded. *Id* at 52. She also explains that she can produce impact estimates for any combination of Defendants and years and/or for any percentage of promotions determined to be unlawful. *Id.* at 52-53.

In other words, Dr. Rosenthal opines how the unlawful marketing here—intended to, and having the effect of, overcoming reluctance to prescribe and use opioids as a class of drugs—increased the usage of all prescription opioids, not just that of a particular Manufacturer Defendant's product. Dr. Rosenthal's analysis provides an important input for the analyses performed by Dr. Cutler and Dr. McGuire linking increased sales to increased harms and increased costs.

[5] The data relied upon and methodologies employed by Plaintiffs' experts are set forth in great detail in the responses filed to Defendants' Daubert motions to exclude their testimony (PD1-PD13) and are incorporated herein. Each expert relied upon data and testimony in discovery materials, peer-reviewed literature in the field of health economics, epidemiology studies, and/or other relevant and admissible evidence in formulating her or his opinions. *See, e.g.,* Rosenthal Rep., Dkt. # 2000-23 at 8-10 (Summary of Opinions), Attachment B; Gruber Rep., Dkt. # 2000-6 at 49-61, 62-69, App'x I.B; Cutler Rep., Dkt. # 2000-4 at 12-13, 17, App'x III.B; McGuire Rep., Dkt. # 2000-17 at 13-14, 16, 17-19, 22-35, App'x IV.B.

[6] The economists' qualifications and expertise are described in detail in Plaintiffs' *Daubert* Roadmap Brief (PD1), and are not repeated herein.

2. Dr. Gruber and Dr. Cutler: Increased Shipments of Opioids Caused Increased Harms.

Dr. Jonathan Gruber and Dr. David Cutler are Professors of Economics at the Massachusetts Institute of Technology, and at Harvard University, respectively. Report of Dr. Jonathan Gruber, Dkt. # 2000-6 at 1; Report of Dr. David Cutler, Dkt. # 2000-4 at 1. Dr. Gruber details the origins, unfolding, and scope of the opioid crisis in the United States. Based on his economic analysis, Dr. Gruber concludes that there is a direct causal relationship between shipments of prescription opioids and misuse of and mortality from these drugs. *See* Gruber Rep., Dkt. # 2000-6 at 8-10, 55-61. He demonstrates that the geographic areas that received higher volumes of per capita shipments of prescription opioids experienced significantly higher rates of opioid misuse and mortality. *Id.* Based on a review of the literature and evidence from Defendants, Dr. Gruber also concludes that there is a direct causal relationship between shipments of prescription opioids and misuse of and mortality from illicit opioids. *Id.* at 8-10, 62-70. Dr. Gruber finds that the significant increases in all opioid mortality are largely unrelated to other factors such as trends in non-opioid drug overdoses, changes in population demographics, or local economic conditions. *Id.* at 8-10, 70-76.

Dr. Cutler, in turn, analyzes the impact of opioid prescription shipments on harms to Summit and Cuyahoga Counties and estimates the annual harms in each county attributable to Defendants' misconduct. Cutler Rep., Dkt. # 2000-4 at 4-5. Using Dr. Rosenthal's estimates of the share of prescription opioids attributable to Defendants' unlawful marketing, Dr. Cutler models and computes first the percentage of certain specific harms attributable to opioid shipments, *id.* at 4-5, 13-14, 17-57, and second, the percentage of these harms attributable to Defendants' misconduct. *Id.* at 4-5, 15, 58-75.

3. Dr. McGuire: Increased Harms Caused Quantifiable Damage to Summit and Cuyahoga Counties.

Dr. Thomas McGuire is a Professor of Health Economics in the Department of Health Care Policy at Harvard Medical School, where he teaches health economics in Harvard's Ph.D. Program in Health Policy. *See* Report of Dr. Thomas McGuire, Dkt. # 2000-17 at 1. Dr. McGuire submitted two separate expert reports. In his "Damages" Report, he quantifies the costs to Summit and Cuyahoga Counties of the harms caused by Defendants' unlawful marketing of opioids. *Id.* at 4-8, 41-46. Dr. McGuire analyzes the extent of spending by the Counties resulting from opioid harms, and then uses Dr. Cutler's results to determine the percentage of those costs attributable to Defendants' unlawful conduct. *Id.* at 41-43. Dr. McGuire is thus able to use econometric analysis and the work of the other economic experts to identify how much of Summit and Cuyahoga Counties' spending went to combating the opioid epidemic, and how much of that was caused by Defendants' misconduct, as opposed to drug use not attributable to the Defendants. *Id.* at 43-46. For purposes of Dr. McGuire's analysis, it makes no difference which opioid overdoses, which babies born with neonatal abstinence syndrome, or which opioids orphans requiring social services were the result of Defendants' conduct. The issue is how many more there were because of Defendants' misconduct and how this increased the costs of addressing these problems. *Id.* at 43. Dr. McGuire estimates these costs over an eleven-year period to be in the billions of dollars. *Id.*, at 77-80. Likewise, in his report on public nuisance, Dr. McGuire opines that "a public nuisance has resulted from the shipment of prescription opioid products into the Bellwether communities, and that this public nuisance has had a widespread, devastating, and long-lasting impact on both the individual residents of the Bellwether communities and on the Bellwether Plaintiffs themselves . . ." *See* McGuire Rep., Dkt. # 2000-18 at 7.

D. PLAINTIFFS' SOMS EXPERTS PROVIDE EVIDENCE OF CAUSATION OF HARM AND DAMAGES BY DISTRIBUTION MISCONDUCT.

Plaintiffs designated and provided reports for four experts pertaining to Defendants' failure to control the supply chain for opioids and to meet their statutory obligations: Dr. Seth Whitelaw, Dr. Craig McCann, James E. Rafalski, and Lacey Keller. These experts provide opinions about deficiencies in Defendants' SOM programs and analyze data that was available to Defendants to show what they would have found if they had had compliant programs. Their opinions provide important evidence that Defendants' violations of the CSA caused them to fail to discover tens of thousands of suspicious orders, which, as Drs. Cutler, Gruber, and McGuire separately analyze, independently contributed to a public nuisance and caused Plaintiffs to suffer enormous harms and incur hundreds of millions of dollars in damages.

1. Dr. Whitelaw: Defendants' Compliance Programs Are Characterized by Systemic Failures.

Dr. Seth Whitelaw is a lawyer with expertise in corporate compliance in the pharmaceutical industry. He teaches monitoring and auditing to law students and working professionals enrolled in Mitchell Hamline School of Law's Healthcare Compliance Certificate program. Whitelaw Rep., Dkt. # 2000-26 at 1-2. Dr. Whitelaw provides opinions about industry standards and corporate compliance practices in the U.S. pharmaceutical industry. *Id.* at 4-44. He then assesses the compliance practices of Defendants McKesson, *id.* at 53-100, Cardinal, *id.* at 100-126, AmerisourceBergen, *id.* at 126-159, CVS, *id.* at 159-183, Walgreens, *id.* at 183-208, and Mallinckrodt, *id.* at 208-238, against the standards set forth in his report, and finds systemic failures in each. Dr. Whitelaw also assesses the impact of these compliance failures, looking at these Defendants' shipments of orders that were, or should have been, flagged as suspicious, the total volume of shipments, and at particular downstream pharmacy customers from which diversion was likely, but to whom Defendants continued to ship large quantities

of opioids throughout the opioid epidemic. *See id.* at 54-59, 102-104, 128-131, 161-162, 186-188, 212-213.

2. Dr. McCann: Defendants Should Have Flagged Up to Two Million Opioid Dosage Units in Cuyahoga and Summit Counties.

Dr. Craig McCann has a Ph.D. in Economics from the University of California at Los Angeles, has extensive training in mathematics, statistics, and econometrics, has taught economics at various universities, has worked for the Securities and Exchange Commission as a senior financial economist, and has published numerous articles about financial markets. Report of Dr. Craig J. McCann, Dkt. # 2000-14 at 1-2. In his primary expert report, Dr. McCann compares ARCOS data produced by the DEA, public ARCOS reports, and Defendants' transaction data produced in discovery, and concludes that the ARCOS data are complete and reliable, and can be used to identify shipments into a state, county, zip code, or individual pharmacy meeting specified criteria. *Id.* at 4. Based on the nonpublic ARCOS data supplemented by Defendants' transaction data and using metrics provided by Mr. Rafalski described below, Dr. McCann calculated the number of orders shipped to Cuyahoga and Summit Counties from 1996 to 2018 that Defendants should have flagged as "suspicious." *Id.* at 56-74. He concludes that between 870,000 to 2,000,000 orders of opioids should have been flagged as suspicious. *Id.* at 58, 63, 66-67, 70-72, 74-76.[7]

3. James Rafalski: Defendants' Failures to Maintain Effective Controls Against Diversion Led to Excessive Quantities of Opioid Pills Flooding the Illicit Market in the Plaintiff Counties.

James Rafalski was a DEA Diversion Investigator for over 12 years. Rafalski Rep., Dkt. # 2000-22 at 4. During that time, he worked on at least eight significant investigations involving the distribution of opioids or other controlled substances and also served as an instructor for multiple

[7] Dr. McCann issued two Supplemental Expert Reports. In the second of these, he processed additional data to attribute Distributors' downstream shipments to the Manufacturers who supplied the particular product that was shipped, thus making it possible to determine which Manufacturers' drugs were included in the orders flagged as suspicious. *See* McCann Second Suppl. Rep., Dkt. # 2000-16.

agency training courses. *Id.* at 5-6. Based on this experience, Mr. Rafalski provides the opinion that there was a systematic, prolonged failure by Manufacturer and Distributor Defendants to maintain effective controls against diversion of opioids into the illicit market and that this failure was a substantial cause of the opioid crisis in the United States and, specifically, in Cuyahoga and Summit Counties. *Id.* at 7, 46.

Mr. Rafalski then identifies five SOM algorithms actually used by some Defendants that shipped substantial amounts of opioids into the Plaintiff Counties. *See id.* at 40-41. Using Dr. McCann's analysis based on the metrics described above, Mr. Rafalski assesses the number of oxycodone and hydrocodone orders shipped to the Plaintiff Counties by five Distributor Defendants—AmerisourceBergen, Cardinal, McKesson, CVS, and Walgreens—that would have been flagged as suspicious using each metric. *See id.* at 41-46. The numbers are stark: they show that the vast majority of oxycodone and hydrocodone orders would have been flagged as "suspicious" (and thus halted pending due diligence) under any of the five metrics. *See id.* at 41-46, Tables A-E. Based on this data and his review of each Defendant's policies used to identify suspicious orders, Mr. Rafalski concludes that Defendants' misconduct in failing to maintain effective controls against diversion led to the excess quantity of opioid pills flooding the illicit market in the Plaintiff Counties. *Id.* at 46.

4. Lacey Keller: Defendants Failed to Identify Millions of Suspicious Prescriptions and Purchases in the Plaintiff Counties.

Lacey Keller holds a Master of Economics degree and is Managing Director for Datamining & Analytics with Gryphon Strategies, Inc., a leading investigation firm, where she created its datamining and analytics division. Report of Lacey R. Keller, Dkt. # 2000-7 at 6-8. Previously, she founded and directed the Research and Analytics Department for the New York State Office of the Attorney General, where she worked extensively on issues relevant to opioids. *Id.* at 6-7. For example, she developed and managed the Office's Community Overdose Prevention Program, using data analytics (based primarily on the DEA's ARCOS data) to determine how best to deploy life-saving naloxone

across New York State. *Id.* at 7. In her report, Ms. Keller applies industry-standard and Defendants' own SOM compliance metrics to analyze data that were available to Defendants and shows how they could have identified orders of unusual size, frequency, or pattern. *Id.* at 9.

Using IQVIA Xponent data, which track every opioid prescription filled based on the doctor who wrote it and the drug that was prescribed, Ms. Keller identifies physicians in the Plaintiff Counties whose prescribing activity would have been flagged by application of Defendants' own SOM metrics (including those used by Mr. Rafalski and Dr. McCann as described above). *See id.* at 16-22. She identifies, for example, physicians in the Plaintiff Counties who were prescribing over 14 to 16 times the average number of opioid prescriptions (7,000-8,000 vs. under 500), *id.* at 33, 40, and whose opioid prescription volume increased by over 1,600 times from 2006 (50 prescriptions) to 2011 (over 42,000 prescriptions), *id.* at 36. She performs a similar analysis with respect to particular pharmacies' prescriptions, identifying, for instance, one pharmacy that purchased enough opioids to supply Cuyahoga County with almost 2 million dosage units in just eight years, *id.* at 63, and another that purchased enough opioids to supply Summit County with over 3 million dosage units in just eight years. *Id.* at 73. In all, Ms. Keller demonstrates that there were millions of prescriptions and purchases of billions of dosage units and MMEs in the Plaintiff Counties that Defendants could have identified as being of unusual size or frequency and deviating from the normal pattern, and yet failed to do so. *Id.* at 9-10.

5. Drs. Cutler, Gruber, and McGuire: Defendants' Distribution Failures Caused the Plaintiff Counties to Incur Hundreds of Millions of Dollars in Damages.

Plaintiffs' economic experts also analyzed the harms and damages to the Plaintiff Counties caused by Defendants' distribution failures. Dr. Cutler provided a separate harms analysis using an estimate provided by Dr. McCann of the share of prescription opioid shipments that would have been avoided in the absence of Distributors' misconduct. *See* Cutler Rep., Dkt. # 2000-4 at App'x III.J, 2-5; *see also* Declaration of David Cutler in Support of Plaintiffs' Memorandum in Opposition to

Defendants' Motion to Exclude David Cutler's Opinions and Proposed Testimony (PD9) (filed concurrently herewith) at 5, n.15, and App'x A, Table A.1.[8] Based on this share, ranging between 41.4 and 82.9% of opioid shipments to the Plaintiff Counties from 1997 to 2016, Dr. Cutler uses the same two approaches he uses for promotion misconduct to provide measures of opioid harms in the Plaintiff Counties due to distribution misconduct. *See* Cutler Rep., Dkt. # 2000-4 at App'x III.J, 3-5; Cutler Decl. at App'x. A, Tables A.4-A.5. Dr. Gruber concurs with Dr. Cutler's opinion that Defendants' distribution misconduct caused a substantial share of Plaintiffs' opioid-related harms. *See* Gruber Rep., Dkt. # 2000-6 at 7-8.

Dr. McGuire incorporates Dr. Cutler's distribution-based harms analysis into his own calculations of distribution-based damages. *See* McGuire Rep., Dkt. # 2000-17 at 5-6, 10, 11-12, and App'x IV.F. Applying his own two approaches to calculating damages, Dr. McGuire concludes that the Plaintiff Counties incurred total damages from 2006 to 2018 of $286.6 to $331.9 million due to Defendants' distribution-related misconduct. McGuire Rep., Dkt. # 2000-17 at App'x IV.F5. Based on his public nuisance analysis, Dr. McGuire is able to attribute $20.056 billion in economic harms from excess deaths and morbidity, neonatal abstinence, child maltreatment, crimes, and other costs tied to Defendants' misconduct. McGuire Rep., Dkt. # 2000-18 at 8.

III. ARGUMENT

A. THE LEGAL STANDARD FOR CAUSATION.

Under Ohio law, a plaintiff must show that a defendant's wrongful conduct was a cause—i.e., both a cause-in-fact and a legal/proximate cause—of damage to Plaintiffs. *In re Gadolinium-Based Contrast Agents Prod. Liab. Litig.,* 2013 WL 593993, at *3 (N.D. Ohio Feb. 15, 2013). Courts often use the phrase "proximate cause" to mean both cause-in-fact and legal/proximate cause. *Paroline v. United*

[8] Dr. Cutler explains in his Declaration that Dr. McCann's Supplemental Report is the source of the data inputs for his distribution harms analysis, that the inputs in his original report were preliminary, and that the updated inputs from Dr. McCann are provided in the Declaration.

States, 572 U.S. 434, 444 (2014). Under Ohio law, when multiple wrongdoers each contribute to a combined harm, courts routinely apply the "substantial factor" test to the issue of causation.[9] Indeed, in such cases the substantial factor test "has found general acceptance" and "is an improvement over the 'but-for' rule." Prosser and Keeton, Law of Torts § 41, p. 267 (5th ed. 1984); *see also* Dan B. Dobbs, Paul T. Hayden and Ellen M. Bublick, The Law of Torts § 189, p. 635 (2nd ed. 2011) (succinctly stating the rule as "all defendants who are substantial factors in the harm are factual causes").

1. There is a Genuine Dispute under the Substantial Factor Test.

The threshold inquiry for the substantial factor rule is whether the defendant's wrongful conduct had "a substantial as distinguished from a merely negligible effect in bringing about plaintiff's harm." Restatement (Second) of Torts § 431, comment b (1965). The inquiry can be broken down into two separate questions:

(1) whether "the evidence permits a reasonable finding that the defendant's conduct had some effect" in bringing about plaintiff's harm; and

(2) "whether the effect was substantial rather than negligible."

Restatement (Second) of Torts § 431, comment b (1965).

> "The word 'substantial' is used to denote the fact that the defendant's conduct has such an effect in producing the harm as to lead reasonable men to regard it as a cause, using that word in a popular sense, in which there always lurks the idea of responsibility, rather than the so-called 'philosophical sense,' which includes every one of the great number of events without which any happening would not have occurred."

Horton, 653 N.E.2d at 1202 (quoting Restatement (Second) of Torts § 431, comment a).

[9] *See, e.g., Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990) ("[T]he burden of proof is upon the plaintiff to demonstrate that the conduct of each defendant was a substantial factor in producing the harm."); *Queen City Terminals, Inc. v. Gen. Am. Transp. Corp.*, 653 N.E.2d 661, 669 (Ohio 1995) ("In Ohio, the 'substantial factor' test is used to determine liability when factors other than the negligence of the tortfeasor may have caused the plaintiff's damages.") (citing *Pang*); *Horton v. Harwick Chem. Corp.*, 653 N.E.2d 1196 (Ohio 1995) (requiring proof that exposure to each defendant's asbestos was a substantial factor in causing the injury); *In re: E. I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig.,* 2016 WL 659112, at *63 (S.D. Ohio Feb. 17, 2016) ("The 'substantial factor' language utilized by the Court in the instant action has been acknowledged in numerous Ohio appellate court decisions.").

Deciding whether a defendant's misconduct had a more-than-negligible effect in causing harm is a quintessential jury question. *Queen City Terminals,* 653 N.E.2d at 669 ("The determination of whether an actor's conduct was a substantial factor in producing the plaintiff's injury is a question of fact to be determined by the trier of fact."); *Baldridge v. Wright Gas Co.*, 96 N.E.2d 300, 304 (1951) ("[C]ausation is for the determination of the jury and it is not for the court to substitute its reasoning for that of the jury in a field which belongs peculiarly to the latter."). To be sure, a jury might find that one or more of the Defendants in this litigation had only a negligible effect in bringing about Plaintiffs' harm, but it is nevertheless a question for the jury to answer.

Where, as here, the Plaintiffs have experienced precisely the type of injuries that one would expect Defendants' misconduct to cause, that in and of itself is sufficient to create a triable issue as to causation: "'Once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, he has done enough to withstand summary judgment on the ground of absence of causation.'" *Empire Title Servs., Inc. v. Fifth Third Mortg. Co.*, 2013 WL 1337629, at *9 (N.D. Ohio Mar. 29, 2013) (quoting *BCS Services, Inc. v. Heartwood 88*, LLC, 637 F.3d 750, 758 (7th Cir.2011) (J. Posner)); *see also Liriano v. Hobart Corp.*, 170 F.3d 264, 271 (2d Cir. 1999) ("When a defendant's negligent act is deemed wrongful precisely because it has a strong propensity to cause the type of injury that ensued, that very causal tendency is evidence enough to establish a prima facie case of cause-in-fact."); *Brown v. Wal-Mart Stores, Inc.*, 198 F.3d 244 (6th Cir.1999) (allowing jury to infer causation where harm to plaintiff—injury from item falling from overhead riser—was the expected consequence of Walmart's negligence in failing to adhere to safety guidelines for stocking shelves).

Contrary to Defendants' arguments, this is not an inference based solely on one event following the other (i.e., post hoc ergo propter hoc). The Restatement explains that "[i]f, as a matter of ordinary experience, a particular act or omission might be expected to produce a particular result,

and if that result has in fact followed, the conclusion may be justified that the causal relation exists." Restatement (Second) of Torts § 433B, comment b (1965). "In drawing that conclusion, the triers of fact are permitted to draw upon ordinary human experience as to the probabilities of the case." *Id.* That is, juries are relied upon to use their common sense and common experience to decide what, more likely than not, actually happened. Indeed, "making reasonable inferences about causation is one of the things that juries do best." *Pacific Shores*, 730 F.3d 1142 at 1168 (9th Cir. 2013).

Here, the failure to prevent diversion is deemed wrongful precisely because diversion is expected to cause serious harm to the general public. Indeed, this is the entire reason Congress passed the Controlled Substances Act. As a 2007 letter from DEA to Distributors states:

> The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances . . . must take reasonable steps to ensure that their registration is not being utilized as a source of diversion. Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as *Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people*. . . . **[E]ven just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm**.

Ex. 131 ABDCMDL00269687-9694 at 9687-9688 (citing 21 U.S.C. § 801(2)) (emphasis added). Likewise, the Supreme Court has long recognized the inherent causal relationship between diversion of opioids and harm to the public. *Direct Sales Co. v. United States*, 319 U.S. 703, 710-11 (1943) ("The difference between sugar, cans, and other articles of normal trade, on the one hand, and narcotic drugs, machine guns and such restricted commodities, on the other, aris[es] from the latters' inherent capacity for harm and from the very fact they are restricted . . . ."). Thus, in light of the harms suffered by Plaintiffs, a jury may reasonably conclude that each Defendant's failure to prevent diversion, more likely than not, caused harm to Plaintiffs.

The Manufacturer Defendants' unlawful promotion of prescription opioids likewise is deemed wrongful precisely because it, too, was expected to and did cause serious harm to the public. The Manufacturers' promotional strategy documents showed expected returns on investment—*through increased sales*—of up to 500% for detailing visits to promote prescription opioids and comparable or greater returns for other opioid promotion practices. *See* Rosenthal Rep., Dkt. # 2000-23 at 29-33. At the time Manufacturers engaged in this conduct, the addictive potential of prescription opioids and the need for restraint in their use was widely understood, *see* Gruber Rep., Dkt. # 2000-6 at 13, as was the likelihood of large-scale opioid addiction, abuse, overdoses, illness, and early death resulting from sharply increased use. *See* Courtwright Rep., Dkt. # 2000-3 at 51-54; *see also Direct Sales Co.*, 319 U.S. 703 at 712 (1943) ("Mass advertising and bargain counter discounts are not appropriate to commodities so surrounded with restrictions. They do not create new legal demand and new classes of legitimate patrons, as they do for sugar, tobacco and other free commodities. Beyond narrow limits, the normal legal market for opiates is not capable of being extended by such methods. The primary effect is rather to create black markets for dope and to increase illegal demand and consumption."). Thus, again, in light of the foreseeable harms suffered by Plaintiffs, a jury may reasonably conclude that each Manufacturer's unlawful promotion conduct, more likely than not, caused these harms.

Defendants' argument that they did not cause the *entire* harm (or that Plaintiffs have not apportioned the damages between each Defendant's wrongful conduct, their "innocent" conduct, and the other contributing factors to the opioid crisis) does not negate causation. Rather, that argument is related to the separate and distinct issue of apportionment, if any, of the total damages, an issue not raised by any of the pending motions before this Court. As Prosser and Keeton explains:

> Once it is determined that the defendant's conduct has been a cause of *some damage* suffered by the plaintiff, a further question may arise as to the portion of the total damage sustained which may properly be assigned to the defendant, as distinguished from other causes. The question is primarily *not one of the fact of causation*, but of the feasibility and practical convenience of splitting up the total harm into separate parts which may be attributed to each of two or more causes.

Prosser and Keeton, § 52, p. 345 (emphasis added). *See also People v. ConAgra Grocery Products Co.*, 17 Cal.App.5th 51, 108 (Cal. App. 2017) ("[T]he fact that the remediation plan does not apportion liability between defendants does not infect the court's causation finding."), *cert. denied sub nom. ConAgra Grocery Products Co. v. California*, 139 S. Ct. 377 (2018).[10]

Defendants' arguments related to market share liability also are inapposite. *See*, *e.g.*, Pharmacy Defendants' Brief in Support of Motion for Summary Judgment on Causation at 3-4 (Dkt. 1869) ("Pharm. Defs. Brief"). This theory is used in situations in which only one of many defendants actually caused any harm, but it is impossible to tell which one. *See, e.g., Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187 (Ohio 1998) (rejecting market share theory of liability when a plaintiff's birth defects were caused by DES, but plaintiff was unable to identify which one of the 18 defendant manufacturers actually produced the pills ingested by plaintiff's mother); *but see Minnich v. Ashland Oil Co.*, 473 N.E.2d 1199, 1200 (Ohio 1984) (adopting alternative liability theory when a plaintiff was injured in a chemical explosion, but plaintiff was unable to identify which of the two defendants delivered the chemicals that ultimately exploded). Plaintiffs, however, are not relying on any such theory and have produced evidence sufficient to support a finding that ***each*** Defendant's wrongful conduct contributed to bring about their harm.

2. The Harm Alleged By Plaintiffs Is the Direct and Foreseeable Result of the Defendants' Conduct.

The second prong of causation—proximate causation or legal causation— "is primarily a legal question." *Hunt v. Marksman Prod., Div. of S/R Indus., Inc.,* 656 N.E.2d 726, 728 (1995). Legal cause or

[10] Similarly, to the extent Defendants are asserting a divisibility defense (i.e., that each Defendant is only responsible for causing a portion of the harm), that issue goes to whether each Defendant is jointly and severally liable— also a matter beyond the scope of the present motion, and the burden of apportionment is on the Defendants. "Unless sufficient evidence permits the factfinder to determine that damages are divisible, they are indivisible." Restatement (Third) of Torts: Apportionment Liab. § 26, comment g (2000). "The ultimate burden of proving divisibility is on the party invoking the doctrine." *U.S. Bank Nat. Ass'n v. U.S. E.P.A.,* 563 F.3d 199, 207 (6th Cir.2009) (citing *United States v. R.W. Meyer, Inc.*, 889 F.2d 1497, 1507 (6th Cir.1989); *see also Pakootas v. Teck Cominco Metals, Ltd.*, 905 F.3d 565, 589 (9th Cir. 2018) (citing Restatement (Second) of Torts §433B)) ("[T]he defendant asserting the divisibility defense bears the burden of proof.").

proximate cause has been defined as follows: "A person is not responsible for injury to another if his negligence is a remote cause and not a proximate cause. A cause is remote when the result could not have been reasonably foreseen or anticipated as being the natural or probable cause of any injury." *Halloran v. Barnard*, 2017-Ohio-1069, ¶ 5. "Directness" is also a matter for the "legal cause" prong. *See Ohio v. Carpenter*, 2019 WL 181898 (Ohio Ct. App. Jan. 14, 2019).

This Court has previously found as a matter of law that Plaintiffs' harms are not so far removed from Defendants' misconduct that notions of legal/proximate cause would cut-off their liability for the consequences of their conduct. The Court found, addressing the RICO claims, that:

> Here, Plaintiffs' alleged damages are not speculative, but concrete and ascertainable. No other party can vindicate the law and deter Defendants' alleged conduct because Plaintiffs' asserted damages are not recoverable by any other party. Finally, there is no potential for—and thus no reason for the Court to have to adopt complicated rules to prevent—duplicative recoveries. As none of the *Holmes* concerns are implicated in this case, the Court finds that Plaintiffs have sufficiently alleged proximate cause for their RICO claims.

In re: National Prescription Opiate Litig., Case No. 1:17-MD-2804 (DAP) (Dkt. 1203) at 10 (N.D. Ohio).

Indeed, this Court found that Sixth Circuit precedent allowed a finding of proximate cause for even more remote relationships between conduct and injury. *Id.* (comparing *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 613 (6th Cir. 2004)). The Ohio Supreme Court decision in *City of Cincinnati v. Beretta U.S.A. Corp.*, found that similar governmental entity claims stemming from the aggressive marketing of firearms satisfied the proximate cause test. 68 N.E.2d 1136, 1147 (Ohio 2002).

Nevertheless, Defendants argue their conduct was not a "direct" cause of Plaintiffs' harm because, after all, without the existence of doctors and pharmacists, the pills they distributed would just "*sit on the shelf, causing harm to no one***.**" Distr. Defs. Brief at 3 (emphasis added). This incredible argument, firstly, wrongly assumes opioids are just like any other commodity. They are not.[11] Second,

[11] *See Direct Sales,* 319 U.S. at 710 (stating the difference between opioids and "sugar, cans, etc." is "like that between toy pistols or hunting rifles and machine guns. All articles of commerce may be put to illegal ends. But all do not have inherently the same susceptibility to harmful and illegal use.").

Defendants did not *intend* for the pills to just "sit on the shelf." Instead, Defendants *intended* people to take them. Under Ohio law, "proximate causation is broader with regard to intentional acts than it is for negligent acts." *Iron Workers Local Union No. 17 Ins. Fund v. Philip Morris Inc.,* 23 F.Supp.2d 771, 783 (N.D. Ohio 1998) (J. Gwinn).[12]

There is simply no legal doctrine that would limit Defendants' liability for the consequences of their wrongful conduct. *Cf. Holmes v. Securities Inv'r Protection Corp.,* 503 U.S. 258, 268 (1992). Thus, summary judgment for lack of proximate causation must be denied.

B. THE DEFENDANTS' MISLEADING MARKETING AND FAILURE TO PREVENT DIVERSION CAUSED THE INJURIES SUFFERED BY PLAINTIFFS.

1. Plaintiffs Rely upon Many Sources of Admissible Evidence to Show Causation.

The Plaintiffs' evidence of causation comes from a series of compelling sources: (i) the misconduct itself from which, of course, a jury may infer that the conduct was intended to have the effect of vastly increasing in largely indiscriminate ways the use of prescription opioids; (ii) admissions from Defendants' own files, which document both the success of Manufacturers' efforts to expand usage of opioids and the failure of all Defendants to stop suspicious orders from being shipped; (iii) basic marketing and economic principles (such as the common sense notion that sophisticated drug companies do not spend huge sums of money and time without knowing that those efforts are effective); (iv) a large body of accepted healthcare economics literature showing both that drug promotion increases sales, and that ubiquitous access to opioids, whether through over-promotion or under-detection, leads to widespread use of heroin and fentanyl; (v) associational evidence of the historical relationship of Defendants' misconduct to increased use of and harms from opioids; and

[12] *See also* Restatement (Third) of Torts § 33(b) (2010) ("An actor who intentionally or recklessly causes harm is subject to liability for a broader range of harms than the harms for which that actor would be liable if only acting negligently. In general, the important factors in determining the scope of liability are the moral culpability of the actor, as reflected in the reasons for and intent in committing the tortious acts, the seriousness of harm intended and threatened by those acts, and the degree to which the actor's conduct deviated from appropriate care.").

(vi) expert testimony from healthcare economists and econometricians (such as Drs. Rosenthal and Cutler who, respectively, address the causal relationships of Manufacturers' misconduct to opioid sales, and the increased use of opioids to societal harms in Plaintiff Counties), marketing and medical experts (such as Drs. Perri, Lembke and Schumacher, who opine on how Manufacturers generated widespread misconceptions about the use of opioids), the country's leading FDA expert (Dr. Kessler, who opines that Manufacturers breached laws and duties guiding the promotion of prescription drugs, which requirements are in place precisely to prevent the kind of public health crisis that resulted from Defendants' reckless disregard for the law), corporate compliance and law enforcement experts (like Dr. Whitelaw and Mr. Rafalski, who opine that there was rampant failure by Distributors to maintain effective controls against diversion), and data analytics experts (like Dr. McCann and Ms. Keller, who demonstrate that Defendants' compliance failures caused excess shipments of millions of suspicious orders to the Plaintiff Counties).

In response, Defendants argue that the evidence against them is exceedingly limited or non-existent. *See* Manufacturer Defendants' Brief in Support of Motion for Summary Judgment on Causation, at 1 (Dkt. 1941) ("Manuf. Defs. Brief"); Distributor Defendants' Brief in Support of Motion for Summary Judgment on Causation, at 7 (Dkt. 1897) (Distr. Defs. Brief) ("Plaintiffs' experts do not demonstrate causation ***as to Distributors.***") (emphasis in original). But that is wrong. As described above, several of Plaintiffs' experts present, from an economic perspective, data and opinions about the impact of shipments of prescription opioids on opioid misuse, addiction, mortality and other harms. The economic experts rely upon both aggregate data (such as a regression analysis using detailing contacts, and application of suspicious order-identification metrics to distribution data), and individualized evidence (call notes describing the actual detailing that occurred, analysis of specific companies' SOM compliance practices). Dr. Rosenthal presents an econometric analysis that establishes that Defendants' promotional conduct dramatically increased the shipments of opioids.

Drs. Gruber and Cutler establish that the increases in shipments, due to both over-promotion and under-detection, increased harms in Summit and Cuyahoga Counties. Experts McCann, Rafalski, and Keller establish that Defendants' failures to control the supply chain of opioids and Defendants' wholesale failures to prevent diversion significantly contributed to excess opioid shipments. Drs. Cutler, Gruber, and McGuire then establish the impact of increased shipments of prescription opioids on Summit and Cuyahoga Counties, including those related to crime, public safety and health, and child protection.

This causal showing is buttressed by Plaintiffs' other esteemed experts. Dr. Kessler shows how Defendants' marketing efforts were both deceptive and effective in changing the opioid prescribing habits of physicians. After a review of Manufacturer Defendants' promotional activities, Dr. Lembke concludes that they made "misleading marketing claims to promote . . . misconceptions" about the benefits and risks of opioids "in the absence of reliable science" and "these misconceptions were a primary driver of the massive increase in the sale of opioids and the resulting epidemic of dependence and addiction . . . ." Lembke Rep., Dkt. # 2000-10 at 6. Dr. Schumacher does the same, opining that the "medical standard of care for treating both chronic and acute pain was changed" by Defendants' misleading marketing. Schumacher Rep., Dkt. # 2000-24 at 6. Dr. Gruber focuses on opioid-related mortality and establishes that excess shipments of prescription opioids caused dramatic increases in misuse and mortality from both prescription and illicit opioids. Taken together, these analyses show that Defendants' misconduct, including their misleading promotion and failure to prevent diversion, caused the extensive injuries the opioid epidemic inflicted upon the Plaintiff Counties.

It is well-accepted that expert testimony can establish material fact disputes at the summary judgment stage. As the Sixth Circuit has observed, ". . . expert testimony . . . may provide a basis from which the causal sequence may be inferred." *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 267 (6th Cir. 2001) (citing Prosser and Keeton, § 41, p. 270). Therefore, when evaluating a motion for summary

judgment, if a plaintiff's expert causation testimony is "sufficiently rooted in the available evidence to make out a reasonable theory of causation," the court must deny the motion. *McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 805-806 (6th Cir. 2000); *see also Glaser v. Thompson Med. Co.*, 32 F.3d 969, 977-978 (6th Cir. 1994) (finding plaintiffs' specific causation evidence, in the form of expert testimony, was well-supported and therefore "clearly creates material questions of fact" as to specific causation); *Express Energy Servs. Operating, L.P. v. Hall Drilling, LLC*, 2015 WL 3743795, at *12 (S.D. Ohio June 15, 2015) ("Review of the evidence indicates that the Hall Companies have produced sufficient expert testimony on causation to evade summary judgment.").

A plaintiff's showing of causation at the summary judgment stage can be supplemented and even satisfied by other forms of circumstantial evidence. *See, e.g.*, *Hardyman*, 243 F.3d at 269 ("We also recognize that even without expert testimony on the specific question of causation, Plaintiff adduced sufficient evidence to demonstrate a causal connection . . . ."). The combination of the expert evidence with circumstantial evidence is enough to create a jury question on causation. *In re Neurontin Mktg. & Sales Practices Litig. (Harden)*, 712 F.3d 60, 68 (1st Cir. 2013); *see also In re Neurontin Mktg. & Sales Practices Litig. (Aetna)*, 712 F.3d 51, 58 (1st Cir. 2013) (observing that plaintiffs' evidence "included not only aggregate statistical evidence, but circumstantial evidence . . . . It should have been left to a jury to weigh the aggregate and circumstantial evidence of causation . . . ."). Sufficient circumstantial evidence can include showings of temporal relationships between conduct and harm. *See Bradley v. CSX Transportation, Inc.*, 2009 WL 10689055, at *6 (N.D. Ohio) (holding temporal proximity can assist in supporting claims of a specific causation) (internal citation omitted).

Here, even Defendants confess they "played a role" in fueling the opioid epidemic, *see* Nathan Hartle Dep. (07/31/18), Dkt. # 1962-23 at 292:19-292:4, and that "[m]anufacturers fueled the use of prescription pain killers." Ex. 82, MCKMDL00336833 at 4. McKesson's Director of Regulatory Affairs, when asked "would you agree that McKesson played a role, they didn't cause it all, but played

a role in the crisis that we have in America today as it relates to prescription opioids" admitted that "we did play a role as a distributor, yes." Ex. 132, Deposition of Michael Oriente, July 19, 2018 at 324:17-325:4. Dr. Wright — after joining Purdue — authored a study concluding that the amount of diversion and non-medical use of opioids was directly associated with the number of pills in circulation. Dasgupta et al., *Association between non-medical and prescriptive usage of opioids*. Drug & Alcohol Dependence 82:135-42 (2006). The Manufacturers' former KOL — Dr. Portenoy — also describes how the Manufacturers' conduct led to the opioid crisis. *See* Ex. 145, Portenoy Declaration at 30-31. These admissions are significant, as a defendant's own admissions and statements support a showing of causation. *See In re Meridia Prod. Liab. Litig.,* 328 F. Supp. 2d 791, 810 (N.D. Ohio 2004), *aff'd sub nom. Meridia Prod. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861 (6th Cir. 2006). This circumstantial evidence weights strongly against summary judgment.

2. Plaintiffs Can and Do Prove Causation Using Aggregate Proof Models.

a. Statistical Analysis of Aggregate Proof is Widely Accepted by Courts.

Courts routinely allow parties to prove elements of their claims or defenses, including causation, using statistical analysis of aggregate evidence. *See*, *e.g.*, *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016) ("A representative or statistical sample, like all evidence, is a means to establish or defend against liability."); *In re Neurontin Mktg. & Sales Practs. Litig. (Kaiser)*, 712 F.3d 21, 42 (1st Cir. 2013) ("[C]ourts have long permitted parties to use statistical data to establish causal relationships."); *Paige v. Calif.*, 291 F.3d 1141, 1148 (9th Cir. 2002) ("With regard to the first two arguments against the aggregation of data, it is a generally accepted principle that aggregated statistical data may be used where it is more probative than subdivided data."); *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 794 (6th Cir. 2002) ("[R]egression analyses, a yardstick test and a before-and-after test . . . are generally accepted methods of proving antitrust damages."); *U.S. ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549, 560 (E.D. Tenn. 2014) ("[C]ourts now consider mathematical and statistical methods

to be well recognized as reliable and acceptable evidence in determining adjudicative facts.") (citations and internal quotations omitted).

Courts accept statistical analyses of aggregate proof because they are reliable and often highly probative. As the Ninth Circuit explained in *Paige*, aggregate proof may be more reliable than individualized data with respect to causation determinations because a "small sample size may distort the statistical analysis and may render any findings not statistically probative." *Paige*, 291 F.3d at 1148. One commentator elaborates on this point:

> [T]he entire notion that 'particularistic' evidence differs in some significant qualitative way from statistical evidence must be questioned. The concept of 'particularistic' evidence suggests that there exists a form of proof that can provide direct and actual knowledge of the causal relationship between the defendant's tortious conduct and the plaintiff's injury. 'Particularistic' evidence, however, is in fact no less probabilistic than is the statistical evidence that courts purport to shun.

David Rosenberg, *The Causal Connection in Mass Exposure Cases: A 'Public Law' Vision of the Tort System*, 97 HARV. L. REV. 851, 870 (Feb. 1984).

In some settings, statistical analysis of aggregate data may also be the *only* evidence that is reasonably available, making it essential to a party's claim or defense. *See generally Tyson*, 136 S. Ct. at 1046 ("In many cases, a representative sample is 'the only practicable means to collect and present relevant data' establishing a defendant's liability.") (quoting *Manual for Complex Litig.* § 11.493, p. 102 (4th ed. 2004)). One such setting is where, like here, the acts of multiple wrongdoers combine to produce a common harm. *See Paroline v. U.S.*, 572 U.S. 434, 452 (2014) ("[I]t would be nonsensical to adopt a rule whereby individuals hurt by the combined wrongful acts of many (and thus in many instances hurt more badly than otherwise) would have no redress, whereas individuals hurt by the acts of one person alone would have a remedy. These are the principles that underlie the various aggregate causation tests the victim and the Government cite, and they are sound principles.").

There is thus no serious question that statistical analysis of aggregate data like that provided by Plaintiffs' economic experts is, and should be, an accepted form of proof.

b. Parties May Use Aggregate Proof to Establish Common Causation So Long as Their Methodology and Inputs are Scientifically Valid.

Defendants purport to synthesize caselaw in terms of a split of authority regarding use of aggregate proof to assess the causal effects of prescription drug promotional activity. *See* Manuf. Defs. Brief at 19 ("[T]he Seventh Circuit, joining the Second, Ninth, and Eleventh Circuits, recently rejected third-party payors' assertion that they could estimate the effects of the defendant's promotion by using an aggregate regression analysis . . . .") (internal citations and quotations omitted). Defendants' picture of the caselaw is incorrect.

As the U.S. Court of Appeals for the First Circuit concluded with respect to some of the same cases Defendants cite, "[w]e see no split in authority." *In re Neurontin (Kaiser)*, 712 F.3d at 46. In the *Neurontin* litigation, the First Circuit found repeatedly with respect to both admissibility and sufficiency that "regression analysis is a well recognized and scientifically valid approach to understanding statistical data, and courts have long permitted parties to use statistical data to establish causal relationships." *Id.* at 42; *see also In re Neurontin (Aetna)*, 712 F.3d at 57-59 ("Aetna's evidence of but-for causation included not only aggregate statistical evidence, but circumstantial evidence . . . . The absence of evidence from individual doctors in this record does not defeat our conclusion that summary judgment [for defendant] was inappropriately granted. It should have been left to a jury to weigh the aggregate and circumstantial evidence of causation . . . ."); *In re Neurontin (Harden)*, 712 F.3d at 68 ("[T]he Rosenthal report is capable of providing proof of but-for causation. The Harden plaintiffs need not prove causation through the testimony of individual doctors. The combination of the aggregate evidence and the circumstantial evidence was enough for the Harden plaintiffs to overcome summary judgment.").

The Sixth Circuit similarly has held that statistical analysis of aggregate data is both admissible and sufficient as proof of causation of damages in the related antitrust setting. In *Conwood Co.*, *supra*, the Sixth Circuit addressed testimony of an economic expert who "applied a regression analysis,"

which "determined that [plaintiff's] low market growth was due to [defendant's] behavior" and that "increases in [defendant's] exclusionary behavior in a state reduced [plaintiff's] share of sales by a statistically significant amount." 290 F.3d at 780. The Court held that this methodology was "generally accepted," and that it supported the jury's liability verdict and damages award. *See id.* at 793-794. The Seventh Circuit has also held that statistical analysis of aggregate data may provide admissible and sufficient proof of causation of antitrust damages. *See In re High Fructose Corn Syrup Antitrust Litig.*, 295 F.3d 651, 660-61 (7th Cir. 2002) (affirming district court's admission of economic experts' competing regression analyses of price effect in antitrust case; reversing grant of summary judgment).

The allegedly conflicting opinions, including some by courts that elsewhere have admitted aggregate proof models without controversy, in fact do not conflict at all. Rather, each is a case in which the court found that the particular expert's inputs or conclusions did not provide sufficient evidence for the point in issue. In *UFCW Local 1776 v. Eli Lilly & Co.*, the Second Circuit held that an expert's aggregate proof model was insufficient to support class certification in a third-party payor case because it was based on the relationship between the defendant's representations and sales figures at a single point in time. 620 F.3d 121, 135 (2d Cir. 2010); *cf. In re Neurontin (Kaiser)*, 712 F.3d at 46 ("[T]he Second Circuit described the plaintiffs' aggregate evidence of causation as involving only an extrapolation from the fact that the number of off-label prescriptions for Zyprexa fell after Eli Lilly's fraud became known. This does not come close to resembling Dr. Rosenthal's evidence, which examined contemporaneous data that reflected what was actually happening with regard to spending and prescriptions while Pfizer's fraud was ongoing."). Here, notably, Dr. Rosenthal performed the same type of analysis, *see* Rosenthal Rep., Dkt. # 2000-23 at 35-38, 50-51, as was held in *Neurontin* to be both sufficient and qualitatively different from that in *UFCW*.

The other cases Defendants rely upon are similarly inapposite. *See Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 577 (7th Cir. 2017) (affirming Rule 12(b)(6) dismissal where

plaintiffs failed even to identify any study addressing the prescription drug sales practices at issue). In *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, the court affirmed denial of class certification and grant of summary judgment where statistical analysis of plaintiffs' expert, Dr. Rosenthal, focused on point of sales decline and did not control for contemporaneous market factors such as brand drugs moving off-patent and questions emerging about entire class of drugs. 806 F.3d 71, 91-92 (2d Cir. 2015). The court was explicit, however, that "it may be possible in certain circumstances for a putative class to prove causation on a class-wide basis by offering sufficient circumstantial proof . . . to permit the reasonable inference that the third parties in question *must* have relied on the defendant's misrepresentation." *Id.* at 89. The factual record in this case certainly provides "sufficient circumstantial proof."

In sum, courts have consistently held that statistical analysis of aggregate data may be both reliable and sufficient as proof of causation of harm.[13] That is particularly true here, where Plaintiffs present additional direct and circumstantial evidence of causation.

c. Defendants' "Complexity" Argument Is Legally Baseless and Is a Backdoor Challenge to this Court's Prior Proximate Causation Ruling.

The Court also should reject the argument that Plaintiffs' aggregate proof model is too complex. Manufacturer Defendants assert that "courts have rejected far simpler aggregate proof models than the ones Plaintiffs seek to use here." Manuf. Defs. Brief at 19. Whether or not this assertion is correct, it is legally meaningless.

Courts assess aggregate proof models based on their reliability and sufficiency, *not* their simplicity or complexity. In *In re High Fructose Corn Syrup*, the Seventh Circuit recognized that weighing the parties' economic experts' competing regression analyses "requires a knowledge of statistical

[13] Plaintiffs separately demonstrate that their economic experts' statistical analyses are based on well-established and reliable methodologies in the field of public health economics in their concurrently-filed Oppositions to Defendants' *Daubert* Motions addressing Drs. Rosenthal, Gruber, Cutler, and McGuire (PD7, PD8, PD9, PD10, respectively).

inference that [even some] judges do not possess." 295 F.3d at 660. The court's solution, however, was not to exclude the models or to grant summary judgment based on their complexity. Rather, the court suggested steps that the district court could take under FED. R. EVID. 706 to make the regression models easier to understand. *See id.* at 665-66. The court concluded that, "[i]f these suggestions are followed, we think the case can be tried in a reasonable amount of time and be made comprehensible to a jury." *Id.* at 666. This Court thus should reject Defendants' argument here for summary judgment based on the alleged complexity of Plaintiffs' proof model.

The Court also should reject this argument because it is a backdoor challenge to its prior ruling on proximate causation. Manufacturer Defendants argue that in other cases involving aggregate proof models, the "chain of causation was far simpler" than here. Manuf. Defs. Brief at 19. The Court, however, already has addressed the chain of causation that Plaintiffs' economic experts demonstrate and held that it satisfies applicable proximate causation requirements. *See* Dkt. 1203 at 10 ("Under this potential chain of causation, the relationship between Plaintiffs' injury and Defendants' alleged conduct is less remote than [in] prior Sixth Circuit precedent finding proximate cause, and is not too remote to support a finding of proximate cause here."). The Court has already addressed this issue and should reject Manufacturer Defendants' attempt to reargue it here.

The Court also should reject the Distributor Defendants' similar proximate cause argument. Distributors assert that "there are at least five steps—including multiple acts of criminal wrongdoing—standing between Plaintiffs' claimed injury and Distributors' asserted wrongdoing." Distr. Defs. Brief at 17. These steps track or parallel those the Court considered in denying dismissal of the Manufacturer Defendants on proximate cause grounds. *Compare* Distr. Defs. Brief at 17 (Step 2—prescription activity; Step 3—diversion; Steps 4-5—illicit prescription opioid use, harms) *with* Dkt. 1203 at 9 (Steps 2-3—prescription activity; Steps 4-6—licit prescription opioid use, harms). There, the Court held that the causal chain from deceptive promotion to diversion to Plaintiffs' Counties' harms

was proximate. Dkt. 1203 at 9-10 (citing *Trollinger, supra,* 370 F.3d at 619 (upholding RICO claims based on causal chain from illegal hiring practice to depressed wage offers to legal employees' acquiescence)). Here, the causal chain Plaintiffs lay out from Distributor Defendants' failure to prevent diversion to the Plaintiffs' Counties' harms is at least as direct and foreseeable. The Distributors' proximate cause argument thus likewise should be rejected.[14]

d. The Court Also Should Reject Defendants' Remaining Fact-Based Challenges to Plaintiffs' Aggregate Proof Model.

Defendants' fact-based arguments fare no better. Defendants contend that Plaintiffs' proof model fails because it measures the "effects of ***all*** opioids," so that "Plaintiffs are seeking to hold manufacturers liable for the effects of street drugs like heroin and illicit fentanyl" that "the manufacturers had nothing to do with." Manuf. Defs. Brief at 21. This is a heavily contested fact question. Plaintiffs provide substantial proof that Defendants' sharply increased distribution of prescription opioids between the mid-1990s and 2010 did, in fact, cause sharply increased harms from heroin and fentanyl use after 2010. *See* Gruber Rep., Dkt. # 2000-6 at 62-70 (offering opinion based on epidemiology studies linking prescription opioid use to illicit opioid use and economic literature connecting increased prescription shipments to illicit opioid mortality); *see also* Keyes Rep., Dkt. # 2000-9 at 18-24. The Court may not grant summary judgment on this contested material fact question.

[14] The cases Distributor Defendants cite involve causal chains more remote and harms less foreseeable than those demonstrated here. *See*, *e.g.*, *Hemi Grp., LLC v. City of N.Y.*, 559, U.S. 1, 9 (2010) (plur. op.) (chain from seller's failure to report sales to State to State's failure to pass info to City to City's inability to identify purchasers to purchasers' failure to pay sales tax is too remote); *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 457-58 (2006) (chain from seller's failure to charge State sales tax to seller's ability to lower prices to competitor's alleged loss of business is too remote); *Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 405-6 (6th Cir. 2012) (adoption agency's alleged fraud in inducing plaintiffs to enter into business relationship is too remote from separate fraud in agency's conduct after relationship commenced); *City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 615 F.3d 496, 504-5 (6th Cir. 2010) (chain from defendants' provision of funding to non-party lenders' fraudulent issuance of subprime home loans to mass foreclosures to widespread property harms to municipalities' damages from increased expenditures is too remote); *but see City of Cincinnat v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1148 (Ohio 2002) (causal chain from gun manufacturers' manufacturing and sales practices to widespread access by prohibited users to City's increased police, health, and law-enforcement expenses to remedy harms is sufficiently proximate and foreseeable to sustain public nuisance claim). The additional case Pharmacy Defendants cite, *Burnworth v. Harper*, 672 N.E.2d 241 (Ohio Ct. App. 1996), *see* Pharm. Defs. Brief at 6-7, turned on factual causation, not remoteness or foreseeability. *See* 672 N.E.2d at 245 ("[A]ppellant offered no evidence showing that if appellees would have inspected the heaters or ventilation, they would have detected the presence of carbon monoxide or noticed the clogged flue.").

The Court also should reject Defendants' attack on Plaintiffs' aggregate proof model based on Dr. Rosenthal's treatment of all prescription opioid detailing as unlawful. *See* Manuf. Defs. Brief at 21-22. This is exactly what Plaintiffs asked Dr. Rosenthal to do. *See* Rosenthal Rep., Dkt. # 2000-23 at 5-6 (Assignment includes answering question: "Do you have an opinion as to whether the combined effect of the Defendant manufacturers' promotion of prescription opioids since 1995 was a substantial contributing factor in causing an increase in the use of prescription opioids in the Bellwether communities?"). And it was appropriate for her to do this here, just as it was in the *Neurontin* litigation:

> Dr. Rosenthal assumed—at the plaintiffs' direction—that all off-label marketing was fraudulent, then analyzed the relationship between marketing and prescriptions. Such an approach to proving injury from an underlying assumption of unlawful behavior (to be proven to the fact-finder) is well accepted in the antitrust context from which RICO has drawn many of its causation principles.

In re Neurontin (Kaiser), 712 F.3d at 43-44. The same assumption of unlawfulness is warranted here because Defendants' pervasive false marketing altered the medical community's understanding—and the standard of care—concerning the appropriate use of opioids. All of Defendants' promotional activity relied upon and exploited this misunderstanding and thus was presumptively fraudulent, both by its assertion and then its omission, of complete and truthful information on the risks, benefits, and evidence for opioid use. Moreover, even if this assumption were not warranted, Dr. Rosenthal's analysis here does not *depend* on it, as she separately explains that "my backup includes illustrative impact estimates assuming . . . a given percentage of Defendants' promotion is assumed to be lawful." *See* Rosenthal Rep., Dkt. # 2000-23 at 52-53 and Attachment D.

The assumption of unlawfulness, however, *is* warranted. Plaintiffs' expert Dr. Perri examined marketing messages from each Defendant and concluded that each Defendant's marketing revealed an information imbalance between the benefits and the harms of opioids. *See* Perri Rep., Dkt. # 2000-21 at 79 ("[T]he share of voice between benefits and harms was skewed toward benefits."). Most of the training of sales representatives provided little or no information on the risks of opioids. *Id.* When

this information was included, it was with respect to how to minimize objections to opioid use. *Id.* Dr. Perri found that Defendants' "aggressive sales techniques are not appropriate for dangerous prescription medications. At the least, these techniques minimize potential harms; at worst, they dismiss safety issues entirely, providing further support for the proposition that Defendants minimized concerns over the use of opioids." *Id.* at 79-80. *See also* Kessler Rep., Dkt. # 2000-8; Lembke Rep., Dkt. # 2000-10; Schumacher Rep., Dkt. # 2000-24. Thus, there is substantial evidence to support Dr. Rosenthal's assumption that all detailing was unlawful, if not by affirmative misrepresentation, then by omission of corrective information in light of prevailing misunderstandings of appropriate opioid use.

Many government and regulatory agencies have concluded that Defendants' marketing was deceptive or illegal. As early as 2001, FDA expressed concern with Purdue's marketing. A 2011 internal Purdue document memorializing a meeting with FDA reflects FDA's concern that Purdue ". . . is the bad actor," and that "there will be grave concern if this problem continues." Ex. 83, PURCHI-000675080-5085 at 5081. The "problem" appeared to be that "[t]he prescribing of OxyContin is creeping into a whole population of people where it doesn't belong." *Id.* at 5082. Endo, in turn, was repeatedly reprimanded by FDA for its claims that its reformulated "abuse-deterrent" Opana ER formula was safer than the old version. *See* Ex. 84, ENDO-CHI_LIT-00015924-5929. The FDA also repeatedly sent Janssen warning letters relating to "misleading" misrepresentations it made regarding Duragesic for chronic non-cancer pain in its promotional materials. *See* Ex. 85, JAN-MS-00238335-8837; Ex. 86, JAN-MS-00238338-8345. In 2010, FDA observed that Actavis promotional materials for its pain pill Kadian were misleading and that they were "particularly concerning considering the serious and potentially fatal risks associated with the drug." Ex. 50, ACTAVIS0238310-8322 at 8315.

Finally, the Court should reject Defendants' argument that Plaintiffs, by utilizing industry-wide conduct in Dr. Rosenthal's analysis, fail to prove "whether the detailing of any Manufacturing

Defendant caused" any of the alleged harm. Manuf. Defs. Brief at 21. Dr. Rosenthal demonstrates that all Manufacturer Defendants' promotional activities caused the increased prescription opioid sales and shipments that caused the Plaintiff Counties' harms. *See* Rosenthal Rep., Dkt. # 2000-23 at 8-10, 50. Although this analysis necessarily encompasses *each* Defendant's conduct, Dr. Rosenthal did not leave this to implication. Rather, she also analyzed aggregate harm based on the exclusion of each individual Manufacturer Defendant and concluded that "[m]y detailed backup materials, described in Attachment D, demonstrate that I can produce impact estimates for any combination of Defendants and years for which the plaintiffs can prove unlawful conduct." *Id.* at 52-53. *See also* Keyes Rep., Dkt. # 2000-9 at 11, 22 ("the rapid increase in total opioid prescribing levels after the introduction of OxyContin in 1996 was driven by marketing and sales of opioids to physicians due to downplaying risks of harms associated with prescribing [opioids]"). Dr. Cutler likewise explains that his shipments-harms analysis can produce impact estimates on a Defendant-specific basis. *See* Cutler Decl., *supra* (PD9) at 5. In any event, the other forms of evidence set forth above also implicate each Manufacturer Defendant.

In sum, Plaintiffs' use of the aggregate proof models discussed herein is both legally permissible and legally sufficient to establish the causation elements of their claims. Plaintiffs' proof of causation also goes far beyond the aggregate proof models. The evidence developed in this case provides the causal link between Defendants' marketing and promotion and the harms experienced by the Counties.

e. The Court Also Should Reject Defendants' Unsubstantiated Intervening and Superseding Cause Arguments.

Defendants' passing references to allegedly superseding causes of Plaintiffs' harms provide no basis for summary judgment. Manufacturer Defendants assert that "the actual causal chain requires a number of additional steps (which involve numerous superseding and intervening causes) . . . ." Manuf. Defs. Brief at 5; *see also id.* at 10 ("Cutler's analyses simply ignore the numerous intervening and

superseding causes . . . between the alleged unlawful conduct by Manufacturers and opioid mortality from illegal opioids . . . ."); *see also* Distr. Defs. Brief at 18 ("The presence of multiple, independent actors and events—including multiple ***criminal*** acts—further highlights the infirmity of Plaintiffs' theory of causation.") (emphasis in original). These arguments fail for two related reasons.

As an initial matter, Defendants' arguments concerning any alleged "intervening" causes are immaterial. Only superseding causes are sufficient to break the chain of causation. *See Nat'l Credit Union Admin. Bd. v. Ciuni & Panichi, Inc.*, 2019 WL 188472, at *16 (N.D. Ohio Jan. 11, 2019). Defendants' arguments concerning any alleged superseding causes also are unpersuasive. Indeed, the Court already has held that Plaintiffs do not need, as part of their affirmative case, to prove or disprove the allegedly superseding causes that Defendants allege. Defendants identify a seven-step causation chain including allegedly superseding factors pertaining to specific physicians, patients, and addiction outcomes. Manuf. Defs. Brief at 5 n.3. The Court however, envisioned a "far more direct chain of causation" that does not focus on superseding causes. *See* Dkt. 1203 at 9; *see also id.* at 10 ("[T]he Court finds that Plaintiffs have sufficiently alleged proximate cause for their RICO claims."). Defendants' superseding cause argument thus is no more than another attempt to relitigate the Court's previous proximate cause ruling. *See Faiveley Transp. USA, Inc. v. Wabtec Corp.*, 2011 WL 1899730, at *4 (S.D.N.Y. May 13, 2011) (rejecting summary judgment motion as "thinly disguised attempt to relitigate issues" already lost on motion to dismiss).

Second, the Court's prior ruling that Plaintiffs need not prove or disprove these allegedly superseding causes as part of their affirmative case is supported by abundant caselaw holding that these are affirmative defenses for which Defendants bear the burden of proof. As the First Circuit explained in the *Neurontin* litigation:

> Pfizer's argument is a repetition of its assertion that there is an intervening cause—individual physicians' independent medical judgment—which precludes a finding of causation based on aggregate evidence. But "the burden of proving an 'intervening cause'—something which snaps the 'causal chain' (that is, operates as a 'superseding

> cause,' wiping out the defendant's liability) that connects the wrongful act to the [plaintiff's] injury—is on the defendant."

In re Neurontin (Kaiser), 712 F.3d at 45 (quoting *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 757 (7th Cir. 2011)). As Judge Posner, writing for the Seventh Circuit, explained in *BCS*, "[o]nce a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, he has done enough to withstand summary judgment on the ground of absence of causation." *BCS Servs.*, 637 F.3d at 758; *see also e.g., SEC v. Teo*, 746 F.3d 90, 106 (3d Cir. 2014) ("[I]f the issue of an intervening cause is to be raised, it will normally be the defendant's burden to do so."); *Roberts v. Printup*, 595 F.3d 1181, 1189-90 (10th Cir. 2010) ("Whether a third party's intervening cause produced the injury in question is a defense for which the defendant bears the burden of proof."); *Bookhamer v. Sunbeam Prods., Inc.*, 913 F. Supp. 2d 809, 819 (N.D. Cal. 2012) ("Additionally, in negligence cases it is the defendant that bears the burden of showing any superseding cause that would obviate liability.").[15] Since Defendants simply allege the existence of certain intervening or superseding causes without providing proof, these are not grounds for summary judgment.

In any event, an intervening cause is deemed a superseding cause that breaks the chain of causation only if its operation or the consequences of it are unforeseeable. *See* Restatement (Second) of Torts § 442(b). As demonstrated herein, the intervening causes Defendants identify—doctors, pill-mills, criminal distribution, diversion, and consumption—were foreseeable (and were indeed foreseen) results of Defendants' unlawful promotion and distribution and thus do not break the causal chain. In addition, subsequent causes or events are only superseding if they are independent of the

[15] *City of Cleveland v. Ameriquest*, *supra*, cited by Distributor Defendants, Distr. Defs. Brief at 18, is not to the contrary. That case turned not on the mere presence of third parties and potentially superseding causes, but rather on what the Court held to be a too-attenuated chain of causation from the defendants' provision of funding to non-party lenders' fraudulent issuance of subprime home loans to mass foreclosures to widespread property harms to municipalities' damages from increased expenditures. *See* 615 F.3d at 505 ("The involvement of ***so many*** independent actors also reveals why Cleveland's reliance on *Beretta* [*supra*] is misplaced.") (emphasis added).

defendant's wrongful conduct. *Queen City Terminals*, *supra*, 653 N.E.2d at 671. The additional factors identified by Defendants, such as the use of heroin and fentanyl, were not independent of, but the direct result of, the over-supply of prescription opioids; once addicted to prescription opioids, users were compelled to satisfy their addiction with other available drugs. Lembke Rep., Dkt. # 2000-10 at 84-87 (citing extensive evidence connecting prescription opioid to heroin use).

f. Plaintiffs Satisfy Their Burden of Proof on Causation with or without Their Conspiracy Allegations.

As set forth, Plaintiffs can and do establish the causal relationship between the Manufacturer Defendants' unlawful conduct and Plaintiffs' harms through statistical analysis of aggregate data. This evidence is at least as probative of *each* Defendant's liability as would be any allegedly more individuated evidence of causation. *See generally Paige*, 291 F.3d at 1148 (explaining that "aggregated statistical data may be . . . more probative than subdivided data" because "small sample size may distort the statistical analysis and may render any findings not statistically probative."). And the aggregate data is supported by individualized facts set forth herein.

The Court thus should reject Defendants' argument that "[a]lleging a conspiracy does not allow Plaintiffs to prove proximate cause by treating ***all conduct*** by ***all Defendants*** as one, either." Manuf. Defs. Brief at 23 (emphasis in original). That is not what Plaintiffs are doing because that is not what statistical analysis of aggregate data does. Rather, it is a way to prove one or more individual party's claim or its liability. *See*, *e.g.*, *Tyson*, 136 S. Ct. at 1046 ("A representative or statistical sample, ***like all evidence***, is a means to establish or defend against liability.") (emphasis added). So it is here.

With respect to Plaintiffs' RICO marketing and supply chain conspiracy claims, although the foregoing refutes the assertion that Plaintiffs fail to prove causation as to each Defendant, Defendants also are incorrect as to the alleged limits of Plaintiffs' expert analyses. Defendants assert that "[Dr.] Rosenthal analyzes only the relationship between ***all*** nationwide in-person detailing contracts by ***all*** opioid manufacturers and nationwide opioid prescriptions for all opioid medicines—not just

Manufacturer Defendants', and certainly not just the RICO Marketing Defendants.'" Manuf. Defs. Brief at 24-25 (emphasis in original). This is incorrect. As discussed, *supra*, Dr. Rosenthal also analyzes aggregate harm based on the exclusion of each individual Manufacturer Defendant. *See supra*; *see also* Rosenthal Rep., Dkt. # 2000-23 at 52-53.

As to the supply chain Defendants, Defendants also are incorrect that "[Dr.] Cutler did not . . . isolate the conduct of RICO Supply Chain Defendants . . . ." Manuf. Defs. Brief at 25. In fact, Dr. Cutler estimated the harms that would not have occurred in the absence of supply chain misconduct, including that of Manufacturers and Distributor Defendants alike. *See* Cutler Rep., Dkt. # 2000-4 at 4-5, 9-10, App'x III.J. He need not do more than this because Defendants' liability under RICO is joint and several. *See*, *e.g.*, *U.S. v. Corrado*, 227 F.3d 543, 553 (6th Cir. 2000) (criminal forfeiture); *Fleischhauer v. Feltner*, 879 F.2d 1290, 1301 (6th Cir. 1989) (civil damages). In any event, Dr. Cutler, like Dr. Rosenthal, explains that he too can apply his shipments-harms analysis on a Defendant-specific basis. *See* Cutler Decl., *supra* (PD9) at 5. Defendants' conspiracy-based arguments thus do nothing to undermine Plaintiffs' aggregate proof model.[16]

g. Plaintiffs Also Satisfy Their Causation Burden for Public Nuisance.

As Defendants recognize, *see* Manuf. Defs. Brief at 22, Plaintiffs must demonstrate that their unlawful conduct was a substantial contributing factor to the *nuisance*, as opposed to any more individually defined harm. On public nuisance claims, "where the welfare and safety of an entire community is at stake, the cause need not be so proximate as in individual negligence cases." *NAACP v. AcuSport, Inc.*, 271 F. Supp. 2d 435, 497 (E.D.N.Y. 2003); *see also City of New York v. Beretta U.S.A. Corp.*, 315 F. Supp. 2d 256, 282 (E.D.N.Y 2004) ("The tortious actions or omissions of a defendant

[16] Additionally, as laid out in Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Plaintiffs' Civil Conspiracy, RICO and OCPA Claims (PSJ3), the causation standard under the Ohio Corrupt Practices Act is less stringent than RICO causation. *Id.* at 92 and n. 547 (noting that omission of the "by reason of" language in federal RICO statute eliminates the direct injury requirement for this claim).

or defendants need not be the immediate cause of injury to the public. If a defendant's conduct 'remains the dominant and relevant fact without which the public nuisance would not have resulted where and under the circumstances it did,' it may be held liable for setting in motion or being a force in the sequence of events resulting in injury to the public.") (internal citations omitted). In *Cincinnati v. Beretta U.S.A. Corp.*, the Ohio Supreme Court rejected the defendants' argument that causation was "too tenuous and remote" finding sufficient the allegations that, "as a direct result of the misconduct of appellees, appellant has suffered 'actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services.'" 768 N.E.2d 1136 at 1147; *see also White v. Smith & Wesson*, 97 F. Supp. 2d 816, 825 (N.D. Ohio 2000) (Plaintiffs' claims, including public nuisance claims, "are the 'fairly traceable' result of defendants' actions of allegedly designing and manufacturing unreasonably dangerous products.").

Plaintiffs meet this burden through the same quantum of evidence that applies to all of their claims: expert opinion, aggregated and individual proof and the conduct and admissions of Defendants. It cannot be disputed that Defendants' excess shipments caused a public nuisance in Plaintiffs' communities. *See, e.g.,* McGuire Rep., Dkt. # 2000-18 at 21 ("Shipments significantly interfered with public health, safety, peace and comfort of members of the Bellwether communities with continuing and long-lasting effects."); Motion of Plaintiffs Cuyahoga and Summit Counties for Partial Summary Adjudication of their Equitable Claims for Abatement of an Absolute Public Nuisance (Dkt. 1880) at 4-22 (laying out, in detail, how the opioid epidemic is an ongoing public nuisance in Cuyahoga and Summit Counties); *In re Nat'l Prescription Opiate Litig.*, 2019 U.S. App. LEXIS 18502, at *3-4 (6th Cir. June 20, 2019) ("[T]he circumstances in this case, which affect the health and safety of the entire country, are certainly compelling."). Plaintiffs thus more than satisfy their summary judgment burden on their public nuisance claims.

For all of these reasons, Plaintiffs' aggregate proof models (not to mention the extensive circumstantial evidence) provide sufficient evidence of causation of harm with respect to ***all*** claims, including those based on conspiracy, nuisance and otherwise.

h. The Distributor Defendants Are Not Absolved by the Manufacturer Defendants' Concurrent Misconduct.

The Court should reject out of hand the Distributor Defendants' argument that they should be absolved from liability for their own misconduct because of the Manufacturers' concurrent promotional misconduct. Distributors contend that "the proffered testimony of Plaintiffs' experts—that the opioid crisis resulted from an allegedly fraudulent marketing scheme designed to promote the long-term use of opioids for the treatment of chronic pain—establishes that Distributors were ***not*** the cause of Plaintiffs' injuries." Distr. Defs. Brief at 7 (emphasis in original); *see also id.* at 11 ("***Distributors are notably absent from this narrative.***") (emphasis in original). This is incorrect.

Courts in Ohio and elsewhere long have held that "[w]here concurrent causes . . . are the immediate and efficient cause of an injury, it is not competent to take one of them away from the other, and say that it and not the other was the proximate cause of the accident." *Keifer v. Cleveland R. Co.*, 8 Ohio App. 272, 278-79 (1917) (quotation marks and citation omitted); *see also Lippoldt v. Cole*, 468 F.3d 1204, 1220 (10th Cir. 2006) ("That conduct of other people may have concurrently caused the harm does not change the outcome as to [defendants].").

As Plaintiffs' economic expert, Dr. Cutler, explains with respect to Manufacturers' and Distributors' excess shipments and causation of the harms at issue here, "[w]hile this estimate may reflect the harm that could have been avoided in the absence of marketing misconduct, some portion of the harm resulting from such shipments also could have been avoided had CSA registrants, such as Defendant distributors, not acted improperly." Cutler Rep., Dkt. # 2000-4, App'x III.J at 1. Distributors thus are liable parties irrespective of the Manufacturers' concurrent misconduct.

The Court also should reject Distributor Defendants' argument that Plaintiffs fail to prove that their misconduct caused any excess shipments. *See* Distr. Defs. Brief at 12-13; Pharm. Defs. Brief at 11-12. As set forth above, *supra* § II.D, Plaintiffs' SOMs experts demonstrate using Distributors' own algorithms that for the period from 1996 to 2018, Distributors failed to detect between 870,000 to 2,000,000 prescription opioid orders to the Plaintiff Counties that should have been flagged as suspicious. *See* Rafalski Rep., Dkt. # 2000-22 at 40-41; McCann Rep., Dkt. # 2000-14 at 568-60, 62-64, 66-68, 70-72, 74-26. As expert Rafalski testified, it was probable (greater than 51% likelihood) that these "suspicious" shipments were, in fact, diverted into an illicit market. Rafalski Dep., Dkt. # 1969-18 at 189:8-190:22.

Although Distributors argue that even with effective controls, some of these shipments still may have been sent to fill legitimate prescriptions, *see* Distr. Defs. Brief at 13, the Court should reject this argument. For the period in question, Distributors failed to maintain effective, or in some cases *any*, controls to flag suspicious orders. *See* Rafalski Rep., # 2000-22 at 54-68 (Cardinal), 74-81 (McKesson), 91-93 (AmerisourceBergen), 104-13 (CVS), 120-35 (Walgreens), 142-45 (Henry Schein); *see also infra*, § III.B.4. Absent such controls to identify potentially suspicious orders and ensure each order's legitimacy, Distributors could not lawfully ship any of these orders. *See* Memorandum in Support of Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties Under the Controlled Substances Act (Dkt. 1887) at 3-9. Distributors' misconduct thus caused all of the suspicious orders in question to be shipped.

In sum, Distributors' contention that Plaintiffs fail to produce evidence that their misconduct caused excess shipments and the harms and damages alleged is simply incorrect.

3. Manufacturer Defendants' Unlawful Marketing and Promotion Caused a Massive Increase in the Supply of Opioids.

Each Manufacturer Defendant, as shown above, engaged in deceptive marketing campaigns. This conduct achieved its intended goal, which was market expansion. *See* Ex. 87,

PPLPC016000255303. There is substantial literature that pharmaceutical marketing increases drug utilization. *See* Perri Rep., Dkt. # 2000-21 at 29-51. Detailing is particularly effective. *See* Datta A and Dave D., *Effects of Physician-directed Pharmaceutical Promotion on Prescription Behaviors: Longitudinal Evidence*, Health Econ. 26: 450–468 (2017). Robust evidence in this case establishes that Defendants' marketing efforts were successful in increasing the market for opioids. According to ARCOS data, shipments of prescription opioids increased by more than 500% between 1997 and 2010. *See* Gruber Rep., Dkt. # 2000-6 at 16. Overall opioid use is estimated to have increased by 1,448% from 1996 to 2011, with most of this growth occurring between 1996 and 2004. *See* Atluri et al., *Assessment of the Trends in Medical Use and Misuse of Opioid Analgesics from 2004 to 2011*, Pain Physician, 2014;17:E119-E128.

Dr. Russell Portenoy, M.D., KOL, paid speaker, and paid consultant for many of the Defendant Manufacturers, including Purdue, J&J, Cephalon, Endo, Mallinckrodt, and Janssen, *see* Russell Portenoy Dep. (01/24/19), Dkt. # 1969-11 at 14:17-15:13, 135:1-16, 150:9-21, has himself confirmed that Defendants' marketing activities, like those in Ohio, had an influence on prescriber decisions. Indeed, Dr. Portenoy explained that the pharmaceutical messages gave physicians "a sense of assurance that the risks were not significant" and that "the industry decided to market its products, to speak about the benefits . . . without providing the context related to risk and the caution in selecting the right patient, because the message was more likely to lead to marketing advantage if they did not included the negatives." *Id.* at 166:23-167:12. Dr. Portenoy acknowledged that "risk-related concepts . . . tended to be neglected in the marketing materials, and could have had an impact in the way doctors perceived these drugs and led to more prescribing." *Id.* at 168:21-169:5. With respect to Defendant Manufacturers, Dr. Portenoy concluded that, "I've come to conclude that their conduct in marketing without context and without education about risk produced an increase of inappropriate and unsafe prescribing that contributed to the public health problem." *Id.* at 270:16-21. And as Plaintiffs' expert Dr. Mark Schumacher, the Chief of Pain Medicine at the University of California, San Francisco

opines, "the medical standard of care for treating both chronic and acute pain was changed" by the Manufacturers marketing that "trivialized the risk of addiction and exaggerated the benefits of long-term opioid use." Schumacher Rep., Dkt. # 2000-24 at 6.

The evidentiary record is full of Defendants' admissions that their opioid marketing increased the supply of opioids in the market. An internal Mallinckrodt PowerPoint indicates, for example, in connection with their pain medication program, that the larger the salesforce, the larger the company's gross revenue. *See* Ex. 88, MNK-T1_0000228064-8120 at 8105; *see also* Ex. 89, MNK-T1_0000185447-5487 at 5451 ("The Exalgo discussions appear to have a positive impact on physician behavior; with . . . . increasing prescribing of EXALGO post-discussion."). Endo similarly observed, in connection with its pain products, that "[s]ales force detailing is the most impactful tactic, detailing accounts for ~35-65% of all sales & marketing impact." *See* Ex. 90, ENDO-CHI_LIT-00214471 at slide 8. Teva similarly remarked, in connection with its pain pill Actiq, that medical education, specifically "consultant meetings," and "Medical Education Programs" "proved incredibly effective in driving prescription [ACTIQ] growth . . . ." Ex. 91, TEVA_MDL_A_00454816-4871 at 13262, 4855.

Defendants' marketing caused an explosion in sales of the best-known opioids. Purdue recognized that, due to its promotion of OxyContin, "we have been successful beyond our expectations in the non-malignant pain market. Doctors use the drug in non-malignant pain because it is effective and the 'personality' of OxyContin is less threatening to them, and their patients, than that of the morphine alternatives." Ex. 92, PPLP004030150-0151 at 0150. An email to Dr. Richard Sackler explained that Purdue's promotion of OxyContin as being weaker than morphine to differentiate OxyContin from MS CONTIN and make doctors more comfortable using it, was "a success beyond our expectations." Ex. 93, PPLP004030162-0166 at 0162. This led to sales. As Purdue's Executive Director of Marketing stated, "[w]e were able to convince doctors to use OxyContin tablets because of its position in the doctors [sic] mind that is [sic] very different from

morphine." Ex. 94, PPLP004030463-0465 at 0463. Endo's Former Senior director of Oral Pain Solutions Group admits that through marketing and promotion efforts, Opana ER became the number two product in the market segment. *See* Ex. 95, Deposition of Demir Bingol at 38:02-39:20.

Defendants' KOL strategy was also effective in increasing sales. Dr. Perri sets forth the enormous scope of this effort in his Schedule 18 (amounts paid to KOLs) and Schedule 17 (amounts paid to Pain Advocacy Organizations and Professional Societies, and Schedule 14 (Manufacturer's Defendants Use of Advocacy.) *See* Perri Rep., Dkt. # 2000-21 at Schedules 14, 17, 18. The use of KOLs, according to Endo's Mr. Bingol, "help legitimize" the message that opioids can be more widely prescribed. Ex. 95, Bingol Depo. at 95:15-17. When asked at his deposition "[a]nd do you agree that as of February 2010 Endo could drive business with speakers programs," Mr. Bingol answered "yes." *Id.* at 268:1-4.

Front Groups also had their desired impact of increasing sales. Purdue's Gerard Hevern testified that he observed an increase in prescribing after physicians attended "educational" lectures supported by the American Pain Society. *See* Ex. 96, Deposition of Gerard Hevern at 60:16-62:07. As Endo co-founder and former CEO Carol Ammon explained, "thought leaders" "would not only talk about [a company's] products but would really start to move the whole market towards a change in pain management." *See* Blueprint to a Billion: 7 Essentials: The Endo Pharmaceuticals Story, *available at* https://www.youtube.com/watch?v=6fqFOy-bZ1k&t=258s (last accessed July 26, 2019). As fully described and supported by Dr. Kessler, Defendants' promotional efforts completely re-defined and expanded the opioid market place. *See* Kessler Rep., Dkt. # 2000-8.

Dr. Perri, based on his decades of experience in pharmaceutical marketing, concludes: " . . . after reviewing numerous marketing documents describing Defendants' marketing planning and execution, spanning more than two decades, it is my opinion that Defendants' approach to marketing opioids was purposeful, aggressive, and effective in increasing sales. The marketing outcomes,

including Defendants' own internal metrics, support the fact that the Defendants were able to persuade prescribers and other stakeholders to increase the use of opioids for pain." Perri Rep., Dkt. # 2000-21 at 139.

The marketing was particularly successful in the Plaintiff Counties. Between 2006 and 2014, 8.55 billion morphine milligram equivalents ("MME") of opioids were shipped into Cuyahoga County, enough for every resident to consume 742 MME every year. *See* Report of Dr. Craig J. McCann, Dkt. #2000-14 at 6. During this same period, Summit County received 5.16 billion MME of opioids, enough for every resident to receive even more MME's than in Cuyahoga. *Id.* Abuse would be an expected result of this massive, excessive supply. *See* Restatement (Second) of Torts § 433B, comment b (1965) ("[I]f a particular act might be expected to cause a particular result and, if that result has in fact followed, the conclusion may be justified that the causal relation exists.").

Dr. Doug Smith, a Board-Certified Clinical and Forensic Psychologist, served as the Medical Director of the Summit County Alcohol, Drug Addiction and Mental Health Services Board ("ADM") and chairs the Health Committee of the Opiate Task Force ("OTF"). Dr. Smith testified that the Joint Commission's adoption of Pain as the Fifth Vital Sign to measure and treat pain with opioids contributed to the opioid epidemic. Dr. Smith testified that doctors were pressured to meet JCAHO standards and make sure a patient's pain was managed "even though nobody was coming to our hospital for pain." Doug Smith Dep. (11/16/18), Dkt # 1970-24 at 179:2-7. Doctors "shifted under pressure" to prescribe opioid medications more commonly than they would have earlier. *Id.* at 176:25-178:6. It resulted in "pressure on physicians to start handing out Vicodin and Percocet in particular, sometimes OxyContin, when we, otherwise, would have been giving Ibuprofen and Tylenol." *Id.* at 179:2-15. "[W]e were forced, in effect, to start paying a lot of attention to pain and, in effect, forced to start giving Percocet and Vicodin and other things that we certainly would not have been planning to give prior to that." *Id.* at 180:15-20. Greta Johnson, Summit County's 30(b)(6) representative and

former prosecutor, testified that even while doctors were being prosecuted for writing prescriptions, they still were being called on by Manufacturers' sales representatives:

> [T]hese doctors were still being called upon by reps. I mean, we certainly have seen that through the discovery process the number of times -- you know, it's not to excuse the -- the behavior of these docs, certainly, but they definitely had a partner in that crime.

Greta Johnson Dep. (01/15/19), Dkt. #1963-7 at 107:25-111:25.

4. All Defendants' Failures to Detect and Stop Suspicious Orders Led to an Excess Quantity of Opioids In Cuyahoga and Summit Counties That Were Diverted into the Illicit Market.

When Congress enacted the CSA, and when DEA adopted its implementing regulations, they did so out of a recognition that a lack of controls against diversion of controlled substances would lead to real harm in communities across America. That is precisely what has happened. As detailed at length in Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them (Corrected) (Dkt. 1924) at 1-66, none of the Defendants who bring causation motions operated adequate SOMS programs. As a result, Defendants failed to identify suspicious orders, failed to adequately investigate suspicious orders when found, shipped suspicious orders without first determining that there was no risk of diversion, and failed to promptly notify the DEA of such orders. As one McKesson employee noted, in suggesting that the company should notify customers before they reached threshold of 10,000 doses of hydrocodone, so as to avoid lost sales, "[w]e are in the business of selling product." Ex. 134, MCKMDL00543971-3973 at 3973; *see also* Ex. 133, ABDCMDL00000101-0122 at 0105. Under Purdue's monitoring system, "final decisions appeared to primarily rest with the sales department," which Purdue's auditors found to be "problematic." *See* Ex. 149, PPLP004510993-1006, at 1001-02. It is unfortunate – because controls against diversion – if used – would have worked. Indeed, when Walgreens implemented a more robust suspicious order system, sales of OxyContin dropped 18% in three months with a

disproportionate share of the reduction occurring in higher dosages (i.e., the most dangerous pills). *See* Ex. 151, PPLPC045000016166-6172 at 6170.

The resulting opioid epidemic in Cuyahoga and Summit Counties, where its toll of addiction, death, injury, crime, and dislocation has torn apart families and entire communities, entails precisely the harms Congress predicted would happen if companies involved in the distribution of controlled substances failed to take adequate steps to prevent diversion. Plaintiffs have offered considerable expert testimony, supported by significant circumstantial evidence, and admissions by the Defendants themselves that Defendants' failures led directly to the harms within Plaintiffs' communities. This evidence is more than sufficient to raise at least a triable issue of material fact to be resolved at trial by the jury.

Defendants' failures to control the supply chain are not merely technical violations without consequence, but rather a substantial and foreseeable contributing factor in causing the opioid epidemic. Indeed, DEA in 2012 issued an order to show cause against Walgreens' Florida distribution center—one of three such Walgreens centers across the country distributing Schedule 2 controlled substances—because its continued operation constituted "an imminent danger to the public health and safety." Ex. 129, WAGMDL00387653-7707 at 7654. The DEA found that Walgreens' distribution center was ignoring orders and ordering patterns that "should have been obvious signs of diversion occurring at [Walgreens] customer pharmacies." *Id.* at 7657. McKesson concedes that violation of the Controlled Substances Act requirements results in a substantial and detrimental effect on the health and general welfare of the American people. Hartle Dep., Dkt. # 1962-23 at 43:22-44:5.

Contrary to their representations here, *see, e.g.,* Pharm. Defs. Brief at 7-8, the Distributor and Pharmacy Defendants were certainly aware that unlawful shipments of opioids lead to diversion. In 2006, the New York Attorney General and Cardinal Health entered into a settlement agreement concluding that Cardinal Health "repeatedly sold pharmaceuticals to customers that it knew or should

have known were diverting pharmaceuticals." *See* Assurance of Discontinuance, In the Matter of Cardinal Health Inc., available at https://www.sec.gov/Archives/edgar/data/721371/000089882206001540/settlement3.htm . Cardinal Health's Director of Independent Retail Sales acknowledged that more opioid pills in a community "may have" increased the likelihood of diversion and abuse. Ex. 135, Deposition of Raymond Carney at 27:14-28:14. DDM's 30(b)(6) witness admitted they were aware that there was a problem with doctor shopping in Ohio and that those excess pills were being sold in a black market, *see* Jason Briscoe Dep. (12/06/18), Dkt. # 1959-11 at 120:15-122:5. Nonetheless, DDM failed to report a single unusual order to the DEA or the Ohio State Board. *See* Ex. 136, Deposition of Tom Nameth at 124:20-125:2; 155:4-13; 210:3-10. McKesson's Vice President of Regulatory Affairs and former DEA, Gary Boggs, told the company that Distributors have great power to "control the supply to downstream customers," that "Compliance!!!" with regulatory requirements stops diversion, and "major diversion schemes [will] wither away." Ex. 137, MCKMDL00557196 at slide 37, 46. McKesson's Nate Hartle testified that "[u]sing common sense and basic logic, you could assume the more pills that are out there, the more potential for diversion there could be." Hartle Dep., Dkt. # 1962-23 at 268:8-268:15. Mr. Hartle was explicit on causation: diversion "can happen if you don't follow those laws." Hartle Dep., Dkt. # 1962-23 at 59:3-13. AmerisourceBergen's 30(b) (6) witness also admitted "if we don't adhere to our effective controls to prevent diversion, yes, diversion could occur." Deposition of Christopher Zimmerman, Dkt. # 1972-16 at 104:7-17. CVS's Vice President of Logistics—Ron Link—was equally clear about the causal connection:

> Q. Well, if the purpose of the system is to prevent diversion and there's no system in place to do it --
> A. Yeah.
> Q. -- then naturally, the chances of diversion increase, correct?
> A. Yes. Yeah.
> . . .

> Q. So these narcotics that have a higher opportunity for diversion when they are not being monitored, those are the same narcotics, according to the DEA, that are causing deaths in this opioid crisis, correct?
> A. Correct.
> Q. And those are the same narcotics that are sold by CVS pharmacies, correct?
> A. Correct.

Ex. 138, Deposition of Ronald Link at 60:1-23.

Thus, it was simply foreseeable, and foreseen by Distributor Defendants, that shipping suspicious orders causes diversion. As the DEA found in *In the Matter of Southwood Pharmaceuticals Inc.*, the failure to maintain suspicious order controls caused diversion of opioids. 72 FR 36487, 26500 (2007) ("In short, the direct and foreseeable consequence of the manner in which Respondent conducted its due diligence program was the likely diversion of millions of dosage units of hydrocodone."). The DEA recognized in *Southwood* that the legal controls imposed by the CSA were "of critical importance in protecting the American people from this extraordinary threat to public health and safety." *Id.* at 36504; *see also Masters Pharm., Inc.*, 80 Fed. Reg. 55418, 55475 (Drug Enf't Admin. Sept. 15, 2015), *affirmed, Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017) (CSA's "core purposes" is to "prevent prescription drug abuse and the diversion of drugs to persons who seek to abuse them.")

Summit and Cuyahoga Counties were flooded with diverted opioids. Shipments from Cardinal Health to Defendant CVS's Store 3322 in Cleveland went from 313,500 dosage units of oxycodone in 2006 to 648,300 dosage units in 2012, a more than 100% increase. *See* Whitelaw Rpt., Dkt. # 2000-26 at 51. Similar high-volume increases occurred in Summit County. For example, a single CVS store in Akron saw its doses of oxycodone from Cardinal Health go from 213,200 dosage units in 2006 to 536,600 units in 2013. *Id.* at 52. At the same time, the CVS store was also receiving shipments of hydrocodone from CVS's distribution center that increased in volume from 257,500 units in 2006 to a high of 450,100 units in 2009. *Id.* Likewise, Walgreens Store 3314, located in Parma, Ohio—which obtained oxycodone and hydrocodone from Walgreens' distribution centers, as well as Cardinal

Health, Anda and AmerisourceBergen—increased its annual number of dosage units by an astounding 214.68% from 2006 to 2010. *Id.* at 187-188.

McKesson also failed to halt dramatic increases in orders from pharmacies in the Plaintiffs' jurisdictions. For example, Acme Pharmacy #30, located in Summit County, in December 2012 asked for its annual threshold of oxycodone to be raised to 840,000 dosage units, more than eleven times the national average of 75,584 doses per year. *See* Ex. 139, MCKMDL00430387; Whitelaw Rpt., Dkt. # 2000-26 at 55. Initially, McKesson did not fill the full request, but by January 2013 they acceded. *See* Whitelaw Rpt., Dkt. # 2000-26 at 56. For the period shortly thereafter (July 2014 - October 2014), eighty-nine percent of the prescriptions filled by Acme Pharmacy were written by physicians at Summit Pain Specialists, a clinic McKesson had received reports about, and had deep concerns regarding, dating back to 2011. *See* Ex. 140, MCKMDL00402074-2086 at 2074; Ex 141, MCKMDL00634936-4937 at 4936.

Defendants had access to ample data to monitor suspicious orders sent into Summit and Cuyahoga Counties, including the IQVIA Exponent and "charge-back data." *See* Keller Rep., Dkt. # 2000-7 at 10-12. Reviewing this data, expert Keller established that "there were millions of prescriptions and purchases of billions of dosage units and MME's in Cuyahoga and Summit counties that the defendant manufacturers of opioids (called labelers) could have identified as being of unusual size or frequency and deviating from the normal pattern yet were unreported." *Id.* at 9. Had Defendants applied their own compliance metrics, they would have found that "suspicious orders" were responsible for more than half of all opioid prescriptions filled in Summit and Cuyahoga Counties in the periods 1997-2006 and 2008-2017. *Id.,* at 11. Up to 88.7% and 90.5% of Mallinckrodt's opioid MME's shipped into Summit and Cuyahoga Counties, respectively, were part of suspicious orders. *See* Report of Dr. Craig J. McCann, Dkt. # 2000-16 at 9-19. As Karen Harper, Mallinckrodt's

director of compliance testified, an attempt to improve its policy in 2010 was a "train wreck." *See* Harper Dep., Dkt. # 1962-19 at 324:11-325:12.

A sample of the worst offending ('flagged") prescribers establishes one common pattern: the over-prescribers and the "pill-mills" in the Plaintiff Counties were heavily detailed by the Defendants. Dr. Clive Sinoff was visited 44 times over the course of two years by Purdue representatives promoting OxyContin. *See* Keller Rep., Dkt. # 2000-7 at 34. His prescribing of that drug thereafter almost doubled. *Id.* In 2011, Dr. Guang Yang was the second-highest opioid prescriber in the country (the highest prescriber has been imprisoned for his prescribing patterns). *Id.* at 36. Teva logged 115 sales calls to Dr. Yang from 2006-2014. *Id* at 37. Endo detailed Opana to Dr. Yang 180 times from late 2008 to 2016. *Id.* Purdue representatives called Dr. Yang at least 135 times from 2006-2017. *Id.* And Mallinckrodt logged at least 33 calls to Yang in 2011, 51 in 2012, 44 in 2013, mostly to market the opioid Exalgo. *Id.* at 37-38.[17] And as Joe Rannazzisi, former head of DEA's Office of Diversion Control testified, the pill mill pharmacies and doctors – while perhaps small in volume as an overall percentage – "that small percentage is doing a huge amount of harm." *See* Rannazzisi Dep. (04/26/19), Dkt. # 1969-20 at 194:1-2.

5. The Massive Increase in Prescription Opioid Shipments Caused Increased Opioid-Related Harms.

The scientific literature demonstrates a significant association between increases in opioid supply and the increase in prescription opioid deaths. *See* Keyes Rep., Dkt. # 2000-9 at 21 (describing Fischer, et al. (2013), Paulozzi and Ryan (2006), Wisniewski, et al. (2008)). Thus, Defendants' expansion of the supply of opioids caused an escalation in the harmful effects of the opioid epidemic,

[17] An Akron doctor profiled in Keller's Report, Dr. Adolph Harper, is currently incarcerated for his prescribing of controlled substances. A declaration provided by one of his receptionists described weekly visits from an Endo sales representative who "visited Dr. Harper during regular office hours and would have witnessed the waiting room packed with individuals who appeared to be drug addicts. He would have seen some patients who appeared to be high or who were sleeping." *See* Ex. 156, Declaration of Ramona Harrison.

from both medically-prescribed opioids and "black" market use of prescription opioids. According to Plaintiffs' expert Dr. Keyes, upon an analysis of all relevant literature, "risks of opioid use disorders are substantial after medical use." *Id.* at 15. For example, scientific review shows that up to 29% of chronic pain patients fall victim to opioid use disorder. *See* Keyes Rep., Dkt. # 2000-9 at 12-14 (describing Vowles, et al. (2015)). Indeed, it is surely the case that diverted opioids are disproportionately linked with abuse and addiction. Every diverted pill is headed for non-medical use, which Defendants do not dispute is linked to abuse and addiction. *See, e.g.,* Report of Dr. Robin Lyerla, Dkt. # 1939-21 at 6; Report of Dr. Melanie Rosenblatt, Dkt. # 1939-31 at 46-48; Lembke Rep., Dkt. # 2000-10.

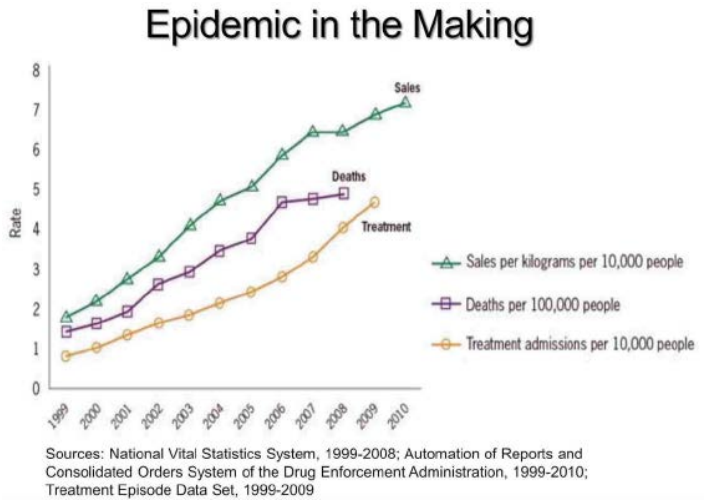
In other words, Defendants' success in flooding the market with opioids, even if for medical use, fueled the epidemic. Plaintiffs' expert, Dr. Gruber, detailing the rapid rise in opioid shipments and the increase in opioid-related mortality since the mid-nineties, concludes increased shipments were a "direct and substantial cause of the rapid growth in mortality from both licit and illicit opioid-related mortality in the past 20 years." Gruber Rep., Dkt. # 2000-6 at 49. Gruber finds that counties with increased shipments experienced far higher opioid-related mortality. *Id.* at 61.

Dr. Perri also draws a clear conclusion based on his professional experience and training as a pharmacist and in pharmaceutical marketing: "Based on the metrics I have seen, there is support for the proposition that Defendants' marketing increased the size of the opioid market, effectively expanding sales and increased the use of these dangerous drugs. These efforts and resources devoted to opioid marketing were spent to change prescribers and other stakeholders' perceptions about opioids. There is a clear association between opioid utilization and patient outcomes, including increased analgesia, side effects, diversion, overdose, and death." Perri Rep., Dkt. # 2000-21 at 143; *c.f. McLean*, 224 F.3d 797 at 805-806 (6th Cir. 2000) (recognizing expert opinion can be enough to create jury question on causation).

Defendants concede as much. Mallinckrodt's former head of security was most explicit:

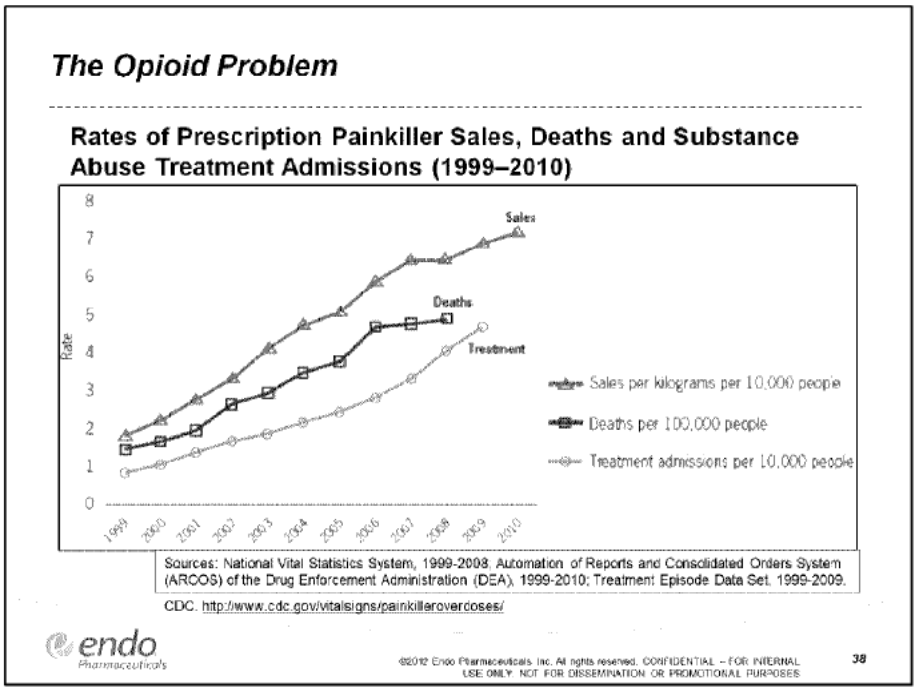
Q. Would you agree that there is an opioid crisis facing this country?
A. I would.
. . .
Q. And what are the causes of this opioid crisis?
A. It would be abuse of narcotics.
Q. Would you agree that over prescription by doctors is a cause?
A. Yes.
Q. Would you agree that the over distribution by pharmaceuticals is a cause?
A. Yes.

William Ratliff Dep. (12/19/18), Dkt. # 1970-1 at 22:10-24:11. Rite-Aid depicts the relationship; as sales increased through the 2000's, deaths increased in lockstep:



Ex. 97, Rite_Aid_OMDL_0034210-4267 at 4224. Testifying about similar data, McKesson's representative noted that opioid sales and opioid deaths were "increasing at a similar rate" and "appear to be related." Hartle Dep., Dkt. # 1962-23 at 293:11-294:2.

Endo representatives admitted responsibility for increases in abuse due to increased supply. Speaking at a 2012 Pain Management Summit, Neil Shusterman, an Endo V.P., stated: "Everybody's seen this slide [below]. I don't see how any of these talks can start without showing the magnitude of the problem. And we felt that being responsible to what we knew to be our specific contribution to the problem was the right thing to do." He then displayed the following slide:



Ex. 98, END00649416-9657 at 9583; Ex. 99, END00648960-9041 at 8997. Mr. Shusterman's comment is very ironic. He recognizes that aggregate data from the National Vital Statistics System and ARCOS is enough to show what he terms "our specific contribution to the problem." Yet before this Court, Defendants' claim aggregate data is insufficient.

Purdue published advertisements admitting that it is "acutely aware of the public health risks analgesics can create, even when taken as prescribed." Ex. 100, Advertisement by Purdue from The New York Times at 1. Kathe Sackler admits that iatrogenic (physician prescribed) opioid use plays a role in the opioid epidemic. *See* Kathe Sackler Dep. (04/01/19), Dkt. # 1970-13 at 130:13-131:2. Ms. Sackler draws an explicit, yet simple, causal link, admitting that the prescription opioid epidemic results from "too much product being there beyond the needs of patients." *Id.* at. 231:15-16. Janssen also admits the connection between market saturation and the terrible harms as the "data show that as the number of prescriptions for opioid drugs increases, so does the frequency of misuse, abuse, overdose and drug-related fatalities." Ex. 101, JAN-MS-01057540-7578 at 7553. Walgreens links the "[i]ncreases in death rates from overdose [as] related to increased availability of opioid prescriptions." *See* Ex. 142,

WAGMDL00608996 at slide 5. These admissions are significant evidence of causation. *See In re Meridia Prod. Liab. Litig.,* 328 F. Supp. at 810 (N.D. Ohio 2004).

The recognition that promotion increased prescribing was reflected in the fact that Manufacturer Defendants set sales goals and provided substantial bonuses to their sales representatives for hitting metrics related to increased sales—and terminated those who did not. Numerous sales representatives interviewed by Plaintiffs confirmed this association in declarations they submitted. *See, e.g.,* Ex. 157, Declaration of William Harris ("Even though Actiq and Fentora were only indicated for cancer pain, Cephalon and Teva's sales goals and intense sales culture perpetuated the astonishing amount of off-label prescriptions for Actiq and Fentora. As a sales representative, if you weren't in line with your peers, you were not going to get a bonus or keep your job."); Ex. 158, Declaration of David Schatz ("Despite its limited indication, the sales goals dictated by Cephalon management required the sales representative to call on more than just oncologists or pain specialists treating cancer patients If a representative stayed within the indicated patient population, there was no way he could meet his sales numbers."; "In general, sales representatives did not want to report suspicious prescribers because they were the money-makers. We did not want to shoot the golden goose."); Ex. 159, Declaration of Dana Sporaa ("During my entire tenure [at Endo] I was eligible to receive bonuses for increasing market share of Opana ER in my territory."); Ex. 160, Declaration of Carol Panara ("My compensation structure included a bonus which was based on my ability to meet a quota. The quota included the number of doctors writing scripts for OxyContin, the number of OxyContin prescriptions written by doctors in my territory, as well as the number of prescriptions within each dosing strength."); Ex. 161, Declaration of Gregory Bowman ("For part of the time that I worked for [Mallinckrodt], dosage was calculated into representatives' bonuses as well; if a doctor prescribed a higher dose of a Mallinckrodt opioid, it counted as extra prescriptions toward the representative's bonus."); Ex. 162, Declaration of Daniel Smith ("Mallinckrodt offered contests to

incentivize sales representatives and would provide monetary incentives or reward points to sales representatives who could reach certain Xartemis prescriptions in a given week. Mallinckrodt held weekly sales calls where management discussed the contests and incentives and made shout-outs and referred to sales reps as 'rock stars' who were growing their sales numbers.")[18]

Of course, there would have been no reason to incentivize and reward sales representatives for greater prescribing if the sales representatives had nothing to do with those sales. And track them they did. As expert Perri's report details, Defendant Manufacturers measured closely whether their marketing tactics were impacting sales. *See* Perri Report 141-143, Schedule 15.[19]

The causal connection between Defendants' marketing and addiction and other harms is buttressed by Defendants' use of the "no ceiling" sales representations detailed above. Purdue made more money if high dose pills were sold, and sales representatives could receive greater bonuses for pushing high dose prescriptions. *See* Ex. 164, Declaration of Shelby Sherman ("There was also a financial incentive to encourage doctors to titrate their patients' doses up . . . : Purdue made more money from higher doses of OxyContin. Sales representatives' bonuses were based on dollar growth in their territories, as opposed to prescription growth, so sales representatives also made more money if doctors prescribed higher doses.") Endo's attempt at promotion of high dose prescriptions also

[18] Distributor Defendants operated with the same incentives. *See, e.g.,* Ex. 155, Declaration of Kirk Klaasesz ("Managers [at Cardinal] told representatives to do whatever they wanted to do to make the customer happy and meet quotas. We told the representatives to sell, sell, sell."); Ex. 163, Declaration of Larry Hunley ("The distribution center managers also received bonuses based on profit and sales and also had an incentive to look the other way on thresholds. Distribution center managers often worried that if McKesson did not approve threshold increase requests, the distribution center might lose good customers and, as a result, managers would receive smaller bonuses. These metrics applied to other senior management, too.")

[19] *See also, e.g.,* Ex. 165, PPLPC041000031311 at slide 0, 44 ("OxyContin growth opportunities," presentation at stating that "increased calls are associated with higher OxyContin TRx growth"); Ex. 166, END00563922-3950 at 3922 (June 26, 2012 Opus Health presentation detailing thousands of new patients); Ex. 167, TEVA_MDL_A_01543547 at slide 32 (describing "hefty" ROI among rh[e]umatologists and emergency medicine doctors, lowest rate of return among oncologists); Ex. 168, TEVA_MDL_A_01543565 at slide 5 ("Linear relationship exists between promotional spend ($) and FENTORA sales"); Ex. 169, ENDO-CHI_LIT-00547089 (speaker programs associated with increase in new patient starts by prescribers who attended programs); Ex. 170, MNK-T1_0001190498 at 190 ("significant difference in prescribing trends post webcast"); Ex. 171, JAN-MS-00405138 at 21 ("Assess pain advocacy landscape and make partner recommendations based on communication and organization ROI").

worked— "The sales message is having a positive impact on physicians, 'approximately 90% indicate that they have prescribed the new strengths recently.'" Ex. 103, ENDO-OPIOID_MDL-04927196-7248 at 7211. This focus on selling higher doses increased the risk of addiction among the public as "the prevalence of opioid use disorder following medical use of prescription opioids . . . escalates with increasing dose . . ." Keyes Rep., Dkt. # 2000-9 at 11 (surveying literature). Higher opioid doses were associated with increased risk of opioid overdose death particularly at doses greater than 100 mg/d. *See* Bohnert et al., *Association between opioid prescribing patterns and opioid overdose-related deaths*. JAMA. 2011;305(13):1315-1321, at p. 1315. Compared to lower dose patients, those with average daily doses of 200 mg or more of morphine (or equivalent), suffer a nearly 3-fold increase in the risk of opioid-related mortality. *See* Gomes et al., *Opioid dose and drug-related mortality in patients with nonmalignant pain*. Arch Intern Med. 2011;171(7):686-691. Walgreens also observed that that "[t]hose who receive higher doses of opioids are at greater risk for overdose." Ex. 142, WAGMDL00608996 at slide 4. The "daily clinical consequence of defendants' myth of no-ceiling dose is reflected in the increasing number of opioid dependent patients." *See* Schumacher Rep., Dkt. # 2000-24 at 37 (reflecting on experience at his hospital).

6. Defendants Are Responsible for the Harms Caused by Illicit Opioid Abuse.

The massive increase of opioids shipped purportedly for medical uses caused increased non-medical use (diversion and abuse). *See* Atluri et al., *Assessment of the Trends in Medical Use and Misuse of Opioid Analgesics from 2004 to 2011*. Pain Physician, 2014;17:E119-E128. Plaintiffs' experts describe in detail how "an additional consequence of the increased supply of opioids was an increase in the incidence and prevalence of non-medical opioid use and non-medical opioid use disorder in the general public." Keyes Rep., Dkt. # 2000-9 at 18. Prescription opioids are diverted from the supply chain for sale and use in the black market. "This non-medical use of opioids, stemming from diversion,

has also contributed to the harm." Keyes Rep., Dkt. # 2000-9 at 16-17. An internal presentation from Endo describes the causal chain:

> "↑ Opioid access & use has ↑ availability of opioids for misuse" "Rx opioid-related deaths, addiction, abuse & misuse are on the rise" "Increase has paralleled increase in Rx opioid sales" "Teens & young adults are fastest growing groups"

Ex. 104, ENDO-CHI_LIT-00241436 at slide 9.

The scope of diversion, as described above, was immense. The Defendants' failure to properly monitor and stop suspicious orders contributed substantially to the diversion. From 1996 through 2018, the Distributor Defendants failed to "flag" and stop as many as 2 million suspicious shipments into Summit and Cuyahoga Counties. McCann Rep., Dkt. # 2000-14 at 58-74. Indeed, the vast majority of orders for oxycodone and hydrocodone shipped there by AmerisourceBergen, Cardinal, McKesson, CVS and Walgreens were suspicious and should have been halted. Rafalski Rep., Dkt. # 2000-22 at 41-47, Tables A-E. It is common sense that Defendants' aggressive marketing and the over-supply of opioids would cause the harms resulting from non-medical use of opioids. According to expert Keyes, "the expansion of non-prescription opioid use would not have occurred without the widespread availability of prescription opioids that were originally dispensed for medical uses, often in greater quantities and doses than necessary, leaving a surplus of opioids that could be diverted for non-medical uses." Keyes Rep., Dkt. # 2000-9 at 20. "Juries are expected to rely on their common sense in resolving questions of causation. Indeed, it is jurors' 'common experience of living on a populated planet' that renders them at least as reliable, if not more so, than a single judge at assessing issues of causation." *Pacific Shores,* 730 F.3d at 1168.

This phenomenon was clearly foreseen by all Defendants. Curtis Wright, former FDA official and Purdue Chief Medical Officer, describes how abuse and diversion are inherent in opioids and at all points in the distribution chain there would be leaks which were a function of volume. Ex. 105, Deposition of Curtis Wright at 225:20-228:1 ("[A]s you put more drugs into the prescriptive drug

flow, as there are more in the marketplace, as there's more in the pharmacies, as they're more in the prescriptions, as there's more in the medicine cabinets at home, more will leak out . . . . [T]he more prescription drugs you had in the marketplace the more drug abuse cases you would have."). Purdue's expert Gerard Hevern admitted in his deposition that one factor in the opioid crisis was "medicines that were available . . . to be diverted." *See* Ex. 96, Hevern Depo. at 58:16-60:07. Endo knew its opioid, Opana, was being sold as a street drug and was being widely misused. Brian Lortie Dep. (01/23/19), Dkt. # 1966-8 at 532:18-537:11, 544:5-550:3, 667:16-678:23. The large variation in shipment volume to various counties show that the volume of opioids that ended up in various locations was not a function of medical need. *See* Gruber Rep., Dkt. # 2000-6 at 52. Rather, its object was to increase sales and profits for the Defendants.[20]

But more pills lead to more deaths. As Cardinal Health was informed, "thousands of deaths have been attributed to supply chain challenges." Ex. 143, DC00011294-1305 at 1297. McKesson agreed, recognizing that prescription drug abuse was on the rise and that by 2006 "opioid painkillers kill more than cocaine and heroin combined." *See* Ex. 152, MCKMDL00403340-3348 at 3342; *see also* Hartle Dep., Dkt. # 1962-23 at 293:11-294:2 (testifying that opioid sales and opioid deaths were "increasing at a similar rate" and "appear to be related"). And as the DEA repeatedly informed "every commercial entity" which "distribute[s] controlled substances": "abuse (nonmedical) of controlled prescription drugs is a serious and growing health problem in this country." Ex. 144, MCKMDL00478906-8909 at 8906. And DEA's Joe Rannazzisi testified:

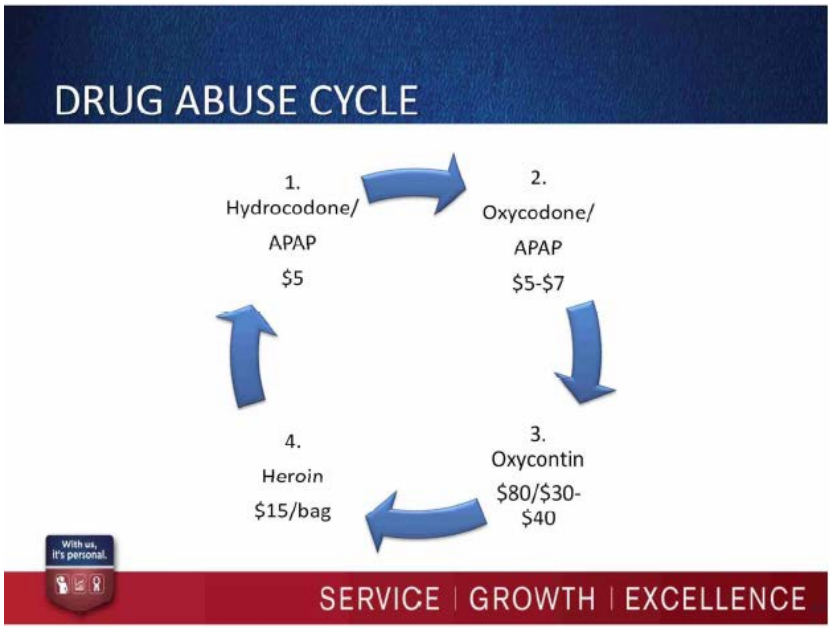
> [Diversion] causes death. That is why our police officer had to start carrying Naloxone because there were overdoses. Some communities were overrun with overdoses. We were losing people left and right. In '15 or '14, we lost over 16,000 people just to the pharmaceuticals . . . .[T]hat's what I meant by people die. Diversion causes death.

[20] A report from one Mallinckrodt sales representative reflected this orientation: "At one national sales meeting, the CEO, Mark Trudeau, asked the sales representatives, 'Who are the most important people to Mallinckrodt?' Representatives suggested answers like patients or employees. But the CEO said, 'The most important thing is our shareholders.' That was an eye-opening moment." Ex. 161, Declaration of Gregory Bowman.

Rannazzisi Dep., Dkt. # 1969-20 at 426:18-427:2.

7. Defendants Are Responsible for the Harms Caused by Heroin and Fentanyl.

Defendants' conduct also substantially contributed to the harms caused by heroin and fentanyl abuse in Summit and Cuyahoga Counties. Plaintiffs' expert Lembke, finds "a clear link between prescription opioid exposure and the subsequent use of heroin and other illicit opioids." Lembke Rep., Dkt. # 2000-10 at 6. The link is established by clear evidence that "prescription opioid use is often the first drug used in a sequence of opioids that results in heroin and fentanyl use." Keyes Rep., Dkt. # 2000-9 at 24. McKesson recognizes that opioid addiction is a direct gateway to illicit heroin use. *See* Hartle Dep., Dkt. # 1962-23 at 320:14-321:10. A graph from Rite-Aid depicts this "Drug Abuse Cycle":



Ex. 106, Rite_Aid_OMDL_0029789-9954 at 9801. Walgreens agrees, and admits that "[i]ndividuals who misuse prescription opioid pain pills are forty times more likely to abuse heroin." Ex. 153, WAGMDL00035671-5683 at 5676.

Studies show consistently that 70-80% of individuals who use heroin started their opioid use with prescriptions opioids. *See* Keyes Rep., Dkt. # 2000-9 at 26-27 (surveying literature). Not surprisingly, prior to 1990, less than 30% of heroin users had "gateway" prescription opioid use. Cicero et al., *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years.* JAMA Psychiatry. 2014;71(7):821-826. doi:10.1001/jamapsychiatry.2014.366. From the 1990's onward, during the period of Defendants' marketing onslaught and the increase in opioid supply, this percentage grew to what recent studies show: 70-80% of heroin users start first with prescription opioids. *See* Keyes Rep., Dkt. # 2000-9 at 26.

That is certainly the experience in Ohio. A 2003 cohort study of ten Ohio heroin users, from Ohio Substance Abuse Monitoring Network, found that half started on prescription opioids. *See* Keyes Rep., Dkt. # 2000-9 at 26. The people on the ground witnessed this first-hand. According to the presentation by Dr. Thomas Gilson, Cuyahoga Medical Examiner, 73% of heroin overdose victims had, within two years of their death, received a legal prescription for a controlled substance. Ex. 107, CUYAH_001397330 at slide 12. Hugh Shannon, Director of the Cuyahoga Medical Examiner's Office testified that Defendants created the illicit market by getting people addicted to prescription opioids. *See* Ex. 108, Deposition of Hugh Shannon (01/24/19) at 84:9-15.

8. Defendants' Misconduct and the Increased Opioid Supply Caused Substantial Harm in Cuyahoga and Summit Counties.

Defendants' marketing and failure to prevent diversion had its intended causal effect in Cuyahoga and Summit Counties. As shown throughout, Defendants' deceptive messages targeted Ohio, resulting in a huge increase in opioid supplies and usage in the Plaintiff Counties. The amount of opioids made available by Defendants' illicit activities is also apparent in the testimony given by city and state officials. As Greta Johnson, Summit County's 30(b)(6) representative and Assistant Chief of Staff to the Executive Director testified: "there is one root cause for why we are here today, and it is 40 million pills in my community in one year." Johnson Dep., Dkt. # 1963-7 at 334:9-12. Dr. Thomas

Gilson testified as Cuyahoga's 30(b)(6) representative that "there are other individuals involved but their responsibility is ultimately referable back to the Defendants." Dr. Gilson further stated that, "I feel the crisis, as we looked retrospectively, falls back to the Defendants. And the drug cartels are part of the sequence of events, if you will. But the crisis is started with the distributors and…the manufacturers." Ex. 109, Deposition of Thomas Gilson (01/22/19) at 200:10-201:5; 209:13-211:1.

Expert Perri shows the immensity of Defendants marketing in Plaintiff Counties, documenting the many sales visits reflected in the call notes of Defendants' sales representatives. *See* Perri Report at Schedule 13 (compiling examples of tens of thousands of visits to doctors within Plaintiff Counties). As shown above, the information conveyed on those visits was false and calculated to increase sales. Dr. Gregory Hall, president pro tem of the Cuyahoga County Board of Health, provides a perfect example of the causal effect of Defendants' conduct. Dr. Hall testified that, as a physician, he prescribed opioids based, in part, upon what he was told by the Defendants' pharmaceutical representatives. *See* Ex. 111, Deposition of Gregory Hall at 224:8-225:13.

As acknowledged by this Court and laid out in detail in Plaintiffs Cuyahoga and Summit Counties' Motion for Partial Summary Adjudication of Their Equitable Claims for Abatement of an Absolute Public Nuisance (Dkt. 1880), the opioid epidemic has been a plague on Summit and Cuyahoga Counties. *See* Dkt. 1203, Opinion and Order (12/19/18) at 9 (J. Polster) ("It is accurate to describe the opioid epidemic as a man-made plague, twenty years in the making. The pain, death, and heartache it has wrought cannot be overstated. As this Court has previously stated, it is hard to find anyone in Ohio who does not have a family member, a friend, a parent of a friend, or a child of a friend who has not been affected."). It has left few individuals and institutions unscathed. Plaintiffs have submitted more than sufficient evidence to establish an issue of material fact with regard to Defendants' role in causing this crisis. In telling moments in their depositions and their own internal documents, Defendants have admitted their role.

IV. CONCLUSION

Plaintiffs have ample statistical and more individuated evidence for each Defendant, to establish, at the very least, a genuine issue of material fact on causation. As demonstrated herein, Defendants' fraudulent marketing and promotion of opioids, as well as their dereliction of duties relating to suspicious ordering and opioid diversion, were the direct cause of the enormous harms experienced by Cuyahoga and Summit Counties. To permit Defendants to escape blame because they each engaged in unlawful acts that, collectively, caused the extensive harm perpetrated upon the Plaintiffs is not permissible. *See, e.g., Paroline,* 572 U.S. at 457 (permitting aggregate causation proof where it would be "nonsensical to adopt a rule whereby individuals hurt by the acts of many would have no redress, while those hurt by the acts of one person alone would"). The law does not permit the Defendants to hide behind the fact that they are part of a group of multiple wrongdoers. In other words, Defendants cannot escape liability simply because there is more than one party (unfortunately) like them that caused the extensive damages experienced by the Plaintiffs and the citizens of Ohio. To find otherwise would result in a severe injustice not justified in law.

For the foregoing reasons, this Court should deny the Manufacturer, Distributor, and Pharmacy Defendants' Motions for Summary Judgment based on proof of causation.

Dated: July 31, 2019

Respectfully submitted,

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